IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff,	
v.	Civil Action No.: 06-222 JJF
IMPAX LABORATORIES, INC., Defendant.	

DECLARATION OF MARY B. MATTERER
IN OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE
IMPAX'S UNCLEAN HANDS DEFENSE AND TO
DISMISS IMPAX'S UNENFORCEABILITY COUNTERCLAIM

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Attorneys for Defendant
IMPAX LABORATORIES, INC.

Dated: May 26, 2006

I, Mary B. Matterer, declare:

1. I am a partner at the law firm of Morris, James, Hitchens & Williams LLP, counsel to Defendant Impax Laboratories, Inc. ("Impax") in this matter.

2. Attached hereto as Exhibit 1 is a copy of a letter from Impax to Plaintiff Wyeth mailed on February 21, 2006.

3. Attached hereto as Exhibit 2 is a copy of Defendant's Answering Brief in Opposition to Plaintiff's Motion to Strike Defendant's Second, Sixth and Seventh Affirmative Defenses, Motion to Dismiss Defendant's Counterclaim that the '164 Patent is Unenforceable, and Motion in the Alternative for a More Definite Statement, filed on December 7, 2004 in *McKesson Information Solutions, LLC v. The Trizetto Group, Inc.*, Civil Action No. 04-1258(SLR) before this Court.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on this twenty-sixth day of May, 2006 at Wilmington, Delaware.

MARY B. MATTERER (I.D. No. 2696)

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of May, 2006, I electronically filed the foregoing document, **DECLARATION OF MARY B. MATTERER IN OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE IMPAX'S UNCLEAN HANDS DEFENSE AND TO DISMISS IMPAX'S UNENFORCEABILITY COUNTERCLAIM,** with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld
Melissa S. Myers
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

Additionally, I hereby certify that on the 26th day of May, 2006, the foregoing document was served as indicated on the following:

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Attorneys for
IMPAX LABORATORIES, INC.

EXHIBIT 1

30831 Huntwood Avenue Hayward, CA 94544
Phone (510) 476-2000 Fax (510) 476-2092

February 21, 2006

Via Federal Express

Wyeth Worldwide Headquarters
Attn.: Legal Department
Five Giralda Farms
Madison, New Jersey 07940

Tracking #8527 7076 2767

Wyeth Pharmaceuticals Worldwide Headquarters
Attn.: Legal Department
500 Arcola Road
Collegeville, Pennsylvania 19426

Tracking #8527 7076 2778

Re: Venlafaxine Hydrochloride Extended Release Capsule Notice Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding U.S. Patent Nos. 6,274,171; 6,419,958; and 6,403,120

Dear Sir or Madam:

I am writing pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 to inform you that Impax Laboratories, Inc. ("Impax") submitted to the United States Food and Drug Administration an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j)(1) and (2)(A), and 21 C.F.R. § 314.94. The ANDA was submitted in order to obtain approval to engage in the commercial manufacture, use, or sale of Venlafaxine Hydrochloride Extended Release Capsules, provided in 37.5 mg, 75 mg and 150 mg dosage strengths.

The Application has been assigned ANDA 78-057 and contains any required bioavailability or bioequivalence data or information.

Impax Laboratories, Inc. intends to market its product before the expiration of U.S. Patent Nos. 6,274,171, 6,419,958 and 6,403,120 (hereinafter "the '171, the '958, and the '120 patents"). All three patents expire on March 17, 2017, but have pediatric exclusivities expiring on September 20, 2017. As required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), the ANDA includes a certification which states that, in Impax's opinion and to the best of its knowledge, the '171, the '958 and the '120 patents are not infringed, are invalid and/or are unenforceable.

As required by 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, a detailed statement of the factual and legal basis for Impax's opinion that the '171, the '958 and the '120 patents are not infringed by our venlafaxine product is attached. Impax reserves the right to assert invalidity or unenforceability of the patents, as well as additional non-infringement arguments, in any litigation commenced against it asserting patent infringement of the '171, the '958 or the '120 patent claims.

Permission to use Federal Express for delivery of this notice and detailed statement was granted by Martin Shimer of the Office of Generic Drugs on February 9, 2006.

Sincerely,
IMPAX Laboratories, Inc.

Mark C. Shaw
Vice-President, Regulatory Affairs and Compliance

Enclosure: Detailed Statement

IMPAX'S DETAILED STATEMENT OF THE FACTUAL AND LEGAL BASES FOR ITS OPINION THAT U.S. PATENT NOS. 6,274,171, 6,419,958, AND 6,403,120 ARE INVALID, UNENFORCEABLE OR NOT INFRINGED BY THE MANUFACTURE, USE OR SALE OF IMPAX LABORATORIES, INC.'S 37.5 MG, 75 MG, OR 150 MG VENLAFAXINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES

A. Impax's venlafaxine HCl Extended Release Product Does Not Contain Microcrystalline Cellulose.

Impax's venlafaxine HCl extended release formulation does not contain microcrystalline cellulose. Our product is a capsule containing sugar spheres coated with a layer of venlafaxine hydrochloride, which is covered with a sustained-release coating. It is not prepared using a spheronization process.

B. There is No Literal Infringement Because Impax's Product Does Not Contain Microcrystalline Cellulose.

The '171 patent contains eight independent and 17 dependent claims. All of the dependent claims are ultimately dependent on claim 1. Claims 1 and 19 are independent claims directed to an extended release formulation that expressly require that each formulation contain at least 50% microcrystalline cellulose. Independent claims 20-25 are generally directed to a method providing certain peak blood plasma levels by administering venlafaxine hydrochloride in certain extended release formulations.

The '958 patent contains six independent claims. Like claims 20-25 of the '171 patent, all six claims of the '958 patent are generally directed to a method of providing certain peak blood plasma levels by administering venlafaxine hydrochloride in certain extended release formulations.

The '120 patent contains one independent and 13 dependent claims. These claims are also method claims generally directed to a method of providing therapeutic peak blood plasma levels of venlafaxine by administering certain extended release formulations.

All of the claims of the '171, '958, and '120 patents either explicitly require that the extended release formulation includes microcrystalline cellulose or implicitly require that the extended release formulation includes one or more additional components to provide the claimed extended release profile.

All of the claims use the phrase "extended release formulation" in the body of the claim. This phrase should be interpreted to mean a formulation comprising venlafaxine hydrochloride and at least microcrystalline cellulose. In reviewing the specification of the patents, it is apparent that applicants defined "extended release formulation" to require microcrystalline cellulose:

> The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising . . . spheroids comprised of venlafaxine hydrochloride, **microcrystalline cellulose** and, optionally . . . .

'171 patent, col. 2, lines 14-18 (emphasis added).

Applicants consistently used this definition to define their invention. In the Detailed Description of the Invention, applicants stated:

> The extended release formulations of this invention are comprised of [venlafaxine hydrochloride] in a mixture with **microcrystalline cellulose** and hydroxypropyl methylcellulose.

'171 patent, col. 2, line 63 – col. 3, line 2 (emphasis added).

The Abstracts of the patents also define the invention as requiring microcrystalline cellulose:

> More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising . . . venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, **microcrystalline cellulose** and, optionally, ...

'171 patent, Abstract (emphasis added).

Furthermore, the specifications only discuss the preparation of spheroids containing microcrystalline cellulose.

> Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose and hydroxypropylmethylcellulose . . . .

'171 patent, col. 5, lines 1-3. See, also, Examples 1-7.

From the specifications, it is also clear that applicants were not intending to include all possible excipients because they argued the superiority of the extended release formulation with microcrystalline cellulose compared to extended release tablets using hydrogel technology.

> Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless . . . .

'171 patent, col. 4, lines 60-64.

Finally, it is significant that Wyeth has already litigated the construction of the phrase "extended release formulation" in Wyeth v. Teva Pharmaceuticals USA, Inc., *et al*., U.S. District Court for the District of New Jersey, Case No. 2:03-cv-01293-WJM-RJH. In the face of Wyeth's arguments for a broader construction, the District Court ruled that the term "extended release formulation" means:

> [A] formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration.

Markman Order, p. 1 (emphasis added).

After receiving the above claim construction order, Wyeth settled with Teva. Furthermore, nothing in the prosecution histories contradicts this interpretation of the claimed invention as requiring microcrystalline cellulose.

Because Impax's venlafaxine extended release formulation does **not** contain microcrystalline cellulose, it does not literally infringe any of the claims of the '171, the '958, and the '120 patents.

C. There is No Infringement Under the Doctrine of Equivalents Because a Required Element is Completely Missing from Impax's Extended Release Formulation.

To infringe under the Doctrine of Equivalents, Impax's formulation would have to include every claim limitation, or its equivalent. A claim limitation is equivalently present only if there are insubstantial differences between the claim limitation and the corresponding aspect of the accused product. Thus, the Doctrine of Equivalents allows

the patent to claim those "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733 (2002) (emphasis added).

A key limitation to the application of the Doctrine of Equivalents is the "All Elements Rule." The Doctrine of Equivalents does not apply if applying the doctrine would vitiate an entire claim limitation.

Impax's extended release formulation has no microcrystalline cellulose, a critical excipient that forms the structure that is coated to provide the extended release profile claimed. Thus, expanding the claims of the patents to cover all products providing the extended release profile, irrespective of whether they contain microcrystalline cellulose, would impermissibly eliminate the critical excipient element in its entirety.

Moreover, the venlafaxine-coated sugar spheres used by Impax are not an insubstantial change. Whereas, the microcrystalline cellulose is critical to the formulation described in the '171, '958 and '120 patents, there is no component of the Impax formulation that serves a similar function because the formulation and process used is completely different.

In conclusion, Impax's venlafaxine HCl extended release formulation containing sugar spheres lacks microcrystalline cellulose, a required element, and therefore does not infringe any claim of the '171, the '958 and the '120 patents, either literally or under the doctrine of equivalents.

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EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MCKESSON INFORMATION SOLUTIONS, LLC, Plaintiff, v. THE TRIZETTO GROUP, INC., Defendant.	)	C.A. No. 04-1258 (SLR)

DEFENDANT'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE DEFENDANT'S SECOND, SIXTH AND SEVENTH AFFIRMATIVE DEFENSES, MOTION TO DISMISS DEFENDANT'S COUNTERCLAIM THAT THE '164 PATENT IS UNENFORCEABLE, AND MOTION IN THE ALTERNATIVE FOR A MORE DEFINITE STATEMENT

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3579 Valley Centre Drive
San Diego, CA 92130
(858) 720-2500

December 7, 2004

TABLE OF CONTENTS

TABLE OF CITATIONS

Statutes

NATURE AND STAGE OF THE PROCEEDING

Plaintiff McKesson Information Solutions, LLC ("McKesson") has sued a smaller competitor, Defendant TriZetto Group, Inc. ("TriZetto"), for patent infringement in an effort to obtain an advantage in the marketplace that it could not achieve by negotiations. Both McKesson and TriZetto compete in the sale of software for health care companies. One function that many customers want, and that both companies offer, is the ability to review physicians' bills for accuracy and reduce unwarranted charges. Between 2001 and late 2003, the parties engaged in extensive negotiations regarding a possible business alliance, but those negotiations failed, ultimately resulting in this lawsuit.

McKesson filed its complaint for patent infringement on September 14, 2004 (D.I. 1) and filed an amended complaint on October 1, 2004 (D.I. 7). McKesson alleges that it owns U.S. Patent No. 5,253,164 ("the '164 patent") and that TriZetto has "made, used, offered for sale and/or sold in the United States a system that infringes one or more claims of the [60-plus page] '164 patent." (D.I. 7). McKesson identifies neither the "system" nor the claims it is asserting. In contrast, in its Answer, TriZetto alleged with great specificity why the '164 patent is invalid and unenforceable (D.I. 10).

Nevertheless, on November 22, 2004, McKesson moved to strike several of TriZetto's defenses and to dismiss its inequitable conduct counterclaim or, in the alternative, for a more definite statement (D.I. 13-14).[1] This is TriZetto's answering brief in opposition to that motion.

---

[1] McKesson filed its motion without first conferring with TriZetto's counsel and without making the certification required by D.Del. LR 7.1.1. It then filed a brief that did not comply with D.Del. LR 7.1.3(c).

SUMMARY OF ARGUMENT

TriZetto has pled its inequitable conduct defense and counterclaim with sufficient particularity by disclosing the acts that form the basis for that defense and counterclaim. Likewise, TriZetto has pled its invalidity defenses sufficiently under Fed. R. Civ. P. 8. Indeed, the allegations that McKesson asserts are indefinite are admissions made by an inventor or by McKesson's predecessor in interest regarding which they have the most knowledge. Finally, TriZetto's unclean hands and patent misuse defense has been pled sufficiently. In any event, if the Court finds that any of TriZetto's defenses have not been pled adequately, the appropriate remedy is to permit amendment.

STATEMENT OF FACTS

TriZetto has pled, and believes that discovery will show, that McKesson and the alleged inventors of the '164 patent knew that the patent was invalid and unenforceable at the time this lawsuit was filed. McKesson's protestations of lack of specificity cannot hide this fact, because most of the allegations pled in TriZetto's affirmative defenses and counterclaims are taken directly from admissions by McKesson's predecessor. For example, it was Marcia Radosevich, the president of McKesson's predecessor, Health Payment Review, Inc. ("HPR"), the original owner of the '164 patent, who admitted in a Harvard MBA case study interview:

> "I couldn't believe that no one else had developed software to review claims. **It was such a simple and ho-hum idea . . .**" (Exh. A, p. 3) (emphasis added).

As pled in the affirmative defenses, prior to any discovery, TriZetto has already uncovered evidence that:

- Dr. Hertenstein, one of the named inventors on the '164 patent, authored and published a journal article, "An Access-oriented Negotiated Fee

Schedule, The Caterpillar Experience" (the "Caterpillar Experience") (Exh. B), more than one year before the application for the '164 patent in which he discussed the claim editing concept disclosed in the '164 patent, making the patent invalid for anticipation under 35 U.S.C. § 102(b) or obviousness under 35 U.S.C. § 103. This paper was also presented before the critical date at the 107th Annual Meeting of the American Surgical Association.

- Dr. Hertenstein failed to disclose the "Caterpillar Experience" prior art article to the patent examiner.
- Radosevich disparaged her company's alleged invention as a "simple and ho-hum idea," thus all but admitting that the patent was invalid for obviousness. (Exh. A, p. 3).
- Radosevich admitted that her colleague Dr. William Ryker wanted to be HPR's Vice-President of Software Development so he "went to the BU [Boston University] bookstore, bought a book on expert systems, and decided how to build the system." (Exh. A, p. 5).
- The alleged inventors failed to disclose this "book on expert systems" to the patent examiner and failed to disclose that reviewing this commonly available college computer science textbook enabled Dr. Ryker to decide "how to build the system." (Exh. A, p. 5).
- The '164 patent seemingly fails to name the correct inventors. For example, Dr. Ryker is not named as an inventor despite the fact that he "decided how to build the system." (Exh. A, p. 5). None of the

> individuals named on the '164 patent are computer programmers – they are all physicians, thus suggesting that: (a) the correct inventors, *i.e.*, the computer programmers, were not named; (b) the "invention" was so obvious it could be made by someone unskilled in the art of programming expert computer systems; or (c) the "invention" had nothing to do with computers.

As Radosevich explained, there was "an incredible amount of money" to be made by someone who owned the rights to a computerized claim review system. (Exh. A, p. 3). Based on the limited investigation that TriZetto has been able to conduct, it appears that the patentees, HPR and McKesson engaged in an ongoing effort to obtain a patent that they knew was invalid and to then enforce the patent, knowing it was invalid, in an effort to gain leverage over TriZetto, a smaller industry competitor.

Thus, in paragraphs 16-18 of its Answer, TriZetto alleged (emphasis added):

> 16. The patent-in-suit is invalid and unenforceable because it was obtained through the intentional failure of the inventors, and/or their agents, to disclose to the Patent Office during prosecution of the patent-in-suit, information material to the patentability of the patent-in-suit, in violation of 37 C.F.R. §1.56.
>
> 17. To the extent now known, and subject to further amplification as to the full extent of the withholding and misrepresentation of information, the inventors and/or their agents made a number of misrepresentations or omissions of material fact to the Patent Office, including but not limited to, false statements and omissions regarding prior art. In particular, and without limitation, the following intentional and material false statements or omissions were made by the inventors and/or their agents, including:
>
> a) the failure by applicants to disclose to the Examiner one of the inventors' own material prior art publications, including "An Access-oriented Negotiated Fee Schedule – The Caterpillar Experience," Ann. Surg. 206(3):349-357 (1987), and a

presentation at the 107th Annual Meeting of The American Surgical Association, Palm Beach, Florida, April 21-23, 1987;

(b) the failure to disclose to the Examiner the fact that the claimed software to review claims was obvious and disclosed in commonly available books on expert systems as admitted by Marcia Radosevich, President of HPR, the assignee of the patent-in-suit, in a case study at the Harvard Business School in 1989;

c) the failure to disclose to the Patent Office that four programming and code review consultants participated in the development of the claimed software as described by Marcia Radosevich to the Harvard Business School; and

d) the failure to disclose to the Patent Office that the invention was conceived by some individuals who were employed by Boston University's Health Policy Institute, and that the work was funded by U.S. Government sponsored research.

18. The above false statements and omitted references and funding information would have been considered by a reasonable examiner to be material to a determination of the allowability of the patent claims, and on information and belief, said statements and omissions were made with intent to deceive the Patent Office. Had the inventors and/or their agents made accurate representations to the Patent Office, the '164 patent would not have issued. Hence, the patent-in-suit is unenforceable for inequitable conduct.

Simply put, serious questions exist regarding the validity and enforceability of the '164 patent. TriZetto has fully identified the documents to which it has access; it is highly likely, however, that McKesson has other documents supporting TriZetto's affirmative defenses and counterclaims. For now, however, TriZetto has more than adequately pled its affirmative defenses and counterclaims to put McKesson on notice of the issues that will be in contest in this lawsuit. Indeed, McKesson's aggressive attempt to strike these defenses is not because McKesson does not understand what TriZetto will seek to prove, but rather because McKesson

understands perfectly well how damaging the evidence that will come out during discovery will be.

ARGUMENT

I. THE LEGAL STANDARD

Motions to strike affirmative defenses are disfavored. *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del. 1998); *CFMT, Inc. v. Yieldup Int'l Corp.*, 1996 U.S. Dist. LEXIS 22795, *3 (D. Del. 1996). When ruling on such a motion, "the court must construe all facts in favor of the nonmoving party . . . and deny the motion if the defense is sufficient under the law." *Id.* A motion to strike affirmative defenses should only be granted when it is "beyond cavil that the defendant could not prevail on them." *Honeywell Consumer Products, Inc. v. Windmere Corp.*, 993 F. Supp. 22, 24 (D. Mass. 1998). Similarly, dismissal of a counterclaim for an alleged failure to state a claim is appropriate only when it appears beyond doubt that the party can prove no set of facts entitling him to relief. *Revis v. Slocomb*, 765 F. Supp. 1212, 1213 (D. Del. 1991).

II. TRIZETTO'S SEVENTH AFFIRMATIVE DEFENSE IS ADEQUATELY PLED

In pleading its affirmative defense of unenforceability for inequitable conduct, TriZetto has met the requirements of Fed. R. Civ. P. 9(b). TriZetto has pled four independent factual bases for the unenforcability of the '164 patent, any one of which is sufficient to state the defense and defeat McKesson's motion.

This Court evaluates inequitable conduct pleadings under Rule 9(b). *Agere Systems Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 733-34 (D. Del. 2002). Averments of inequitable conduct, however, remain subject to the liberal pleading standard of

Rule 8, which requires only a "short and plain" statement of the claim or defense. *TruePosition, Inc. v. Allen Telecom, Inc.*, 2003 U.S. Dist. LEXIS 881, *17 (D. Del. 2003); *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 703 (3d Cir. 1996).

Thus the "pleadings that disclose the name of the [allegedly withheld] relevant prior art and disclose the acts of alleged fraud fulfill the requirements of Rule 9(b)." *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996). This can be accomplished by a single paragraph which names the title and publication date of at least one allegedly withheld material prior art publication. *TruePosition* at *18. Further, once the pleading standard has been met, "nothing about the particularized pleading requirement acts as a bar to further supplementing those facts as they are uncovered." *Agere*, 190 F. Supp. 2d at 734. Thus, even under the heightened pleading requirement of Rule 9(b), it is appropriate for an accused infringer to refer to "other unspecified items of prior art" as part of a defense or counterclaim of inequitable conduct so as not to be artificially limited to the initially identified prior art. *Id.* As explained below, TriZetto has clearly met this standard.

A. Failure To Disclose The Inventor's Own Journal Article

TriZetto pled in paragraph 17(a) of its Answer, as a basis for inequitable conduct, the failure of one of the patentees to disclose his own prior art journal article to the Patent Office. Specifically, Dr. Robert D. Hertenstein was a co-author of a paper entitled "An Access-oriented Negotiated Fee Schedule: The Caterpillar Experience," which was presented orally at the 107th Annual Meeting of The American Surgical Association, in Palm Beach, Florida. The meeting occurred April 21-23, 1987. The Hertenstein "Caterpillar Experience" paper, together with a transcript of a question and answer session that followed, was subsequently published in the journal ANNALS OF SURGERY, 206(3): 349-357 (September 1987). (Exh. B). The article

unquestionably is prior art, since it is dated more than a year before the patent application for the '164 patent.

The paper describes a system developed by Hertenstein and used by Caterpillar Corporation ("CAT") to reimburse surgeons. In doing so, the "CPT-4 codes are recoded for greater accuracy, when indicated, surgical services that have been incorrectly bundled are rebundled, and the appropriateness of surgical assistant charges is reviewed." (Exh. B). Similarly, the '164 patent is directed to a "System and Method for Detecting Fraudulent Medical Claims Via Examination of Service Codes" which applies certain rules to assist medical claims processors to discover inappropriate coding of CPT-4 codes ('164 Patent, col. 3, ln. 30-42).

Hertenstein's paper is directly related to the system claimed in the '164 patent, as explained in the Harvard Business School case study referenced in paragraph 17(b) of TriZetto's Answer:

> HPR began as a joint research project between Boston University (BU) and Caterpillar, Inc. headquartered in Peoria, Illinois. For many years, Dr. Robert Hertenstein, medical director of Group Insurance at Caterpillar, had reviewed reimbursement claims manually for accidental or intentional errors and saved the company about $500,000-$600,000 a year. For example, Hertenstein often found "unbundling" claim errors – billing separately for the components of a treatment instead of for a less expensive inclusive procedure. Thus, he would look for doctors who submitted an "a la carte" bill of $4,500 for the components of a hysterectomy rather than the $2,400 bundled flat fee.
>
> Concerned about its growing health care claims and its reliance on the skills of one individual, Caterpillar sought the help of BU's Health Policy Institute (HPI). The HPI team working on the Caterpillar project – Drs. Richard Egdahl, George Goldberg and William Ryker – were well-known researchers in health care costs containment who had extensive clinical experience. In the course of their study, the team concluded that an automated system to review claims would produce considerable savings for organizations such as Caterpillar. And, they decided to form a

> private, for-profit company to develop and sell such systems. (Exh. A, pp. 2-3).

Thus, Dr. Hertenstein's prior work, as disclosed in "The Caterpillar Experience," and possibly other publications, is highly relevant to the '164 patent. Yet, it was not disclosed to the Patent Office during prosecution, even as the applicants made arguments about the prior art inconsistent with that paper.

B. Failure To Disclose Radosevich's Admission Of Obviousness And Computer Science Books

In paragraph 17(b) of its Answer, TriZetto provides a second factual basis for inequitable conduct – the admission by Radosevich that the "simple and ho-hum idea" of claim review software was obvious to anyone who reviewed a computer science textbook available at the Boston University bookstore:

> But, we were running out of money, because William Ryker, who's brilliant, decided he wanted to be vice president for software development. He went to the BU bookstore, bought a book on expert systems, and decided how to build the system. (Exh. A, p. 5).

Even though Ryker and Radosevich realized that the system could be built after reading this book, their colleagues, the patentees, failed to disclose this fact to the Patent Office. Moreover, they failed to even cite this book to the Patent Office. McKesson asserts that TriZetto fails to name the commonly available book or books that Dr. Ryker looked at to "decide how to build the system," but McKesson has access to Dr. Ryker, Radosevich, and their notes regarding the development of the system, which TriZetto does not. Here, the owner of the patent has admitted access to the prior art publication and admitted the effect of that prior art. All that is missing is the name of the book, which the patentee knows. During discovery, TriZetto will seek to learn the name of that book.

Radosevich's admission not only suggests that a layman, using a commonly available book on expert system design, could design the software system disclosed in the patent-in-suit, but also raises a question as to inventorship, because Dr. Ryker is not named as an inventor on the patent-in-suit. On the other hand, if the "invention" is not the software implementation, then this focuses the scope of the "invention" even more narrowly on the "database containing medical service codes and relationships among the codes" as the point of alleged novelty for the patent-in-suit. In other words, it makes Dr. Hertenstein's work disclosed in the "Caterpillar Experience" article even more relevant.

C. The Failure To Name The Programmers As Inventors

Paragraph 17(c) of TriZetto's Answer, sets forth the third basis for inequitable conduct -- the applicants' failure to disclose the fact that individuals other than the named inventors may have developed the claimed invention. In discussing the development of the HPR system, Radosevich admitted:

> We now have on staff three-full time employees and five full-time consultants – two programmers (the two in Iowa), two product developers – **who generate the coding rules** – and one salesperson . . . (Exh. A, p. 6) (emphasis added).

Thus, at least four individuals with some measure of computer science expertise were involved in developing what appears to be a key aspect of the patented HPR system.[2]

McKesson argues that TriZetto's pleading is not specific enough because it does not identify each of these individuals. Again, McKesson misses the point. TriZetto's pleading is based on admissions against interest. That these admissions might not be specific enough is McKesson's problem because they are based on information that is uniquely within McKesson's

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[2] And, as stated above, Dr. Ryker may also have been an unnamed inventor.

possession. Presumably, Radosevich or Ryker can identify the individuals that they hired to develop the "coding rules" and other aspects of the HPR system on which the '164 patent was based.

McKesson also argues that the fact that consultants participated in developing the "commercial product" has no bearing and cites case law on the differences between conception and reduction to practice in establishing inventorship. Whatever the facts on conception and reduction to practice may turn out to be, however, TriZetto has adequately pled the failure to disclose the consultants as part of its inequitable conduct defense.

D. The Failure To Disclose Government Funding

TriZetto pled in paragraph 17(d) of its Answer that the applicants appear to have failed to disclose to the Patent Office the fact that one or more of the alleged inventors of the '164 patent was employed by Boston University's Health Policy Institute ("HPI") and that their work related to the '164 patent was funded by U.S. Government sponsored research. As quoted above, all of the HPR principals were employed by HPI. In the same article, Radosevich speculated that the solution to HPR's funding problems would be to use grant money:

> And we only have a couple of weeks' worth of cash left. Beyond that, I suppose we could ask BU's venture capital fund for a short-term loan. Dick Egdahl also has some grants at the HPI, and we could put more people on the Institute payroll and pay the Institute back when we get some revenues. (Exh. A, p. 6).

This response fits with what appears to be the overall pattern and practice of HPR and the patentees -- taking public domain ideas and efforts of others and repackaging them as their own alleged inventions -- and obtaining patent protection based on these misconceptions. It is thus supportive of TriZetto's allegations of inequitable conduct. In challenging the sufficiency of this factual allegation, McKesson relies on district court case denying a motion for summary

judgment that a patentee committed inequitable conduct. *Trinity Indus. v. Rd. Sys.*, 235 F. Supp. 2d 536 (E.D. Tex. 2002). That another court denied summary judgment has no bearing on the adequacy of TriZetto's pleading.

TriZetto has pled sufficient factual bases on which to rest its assertion of inequitable conduct. McKesson's motion should be denied.

III. TRIZETTO'S SECOND AFFIRMATIVE DEFENSE IS ADEQUATELY PLED

TriZetto's Second Affirmative defense states that:

> The patent-in-suit is invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and 112. (D.I. 10, ¶ 11).

This affirmative defense is subject to the liberal notice pleading standard of Fed. R. Civ. P. 8. (D.I. 14, p. 3). McKesson, however, makes the novel argument that because the defense is directed to "one or more" of the patentability requirements, "including but not limited to" the relevant statutory provisions, TriZetto has somehow made the defense ambiguous. McKesson's argument is unsupported and should be rejected.

An assertion of patent invalidity, as set forth in TriZetto's Answer, is standard language and readily accepted as meeting the Rule 8(b) requirement. For example, in *Mayo Foundation v. Fonar Corp.*, C.A. No. 97-423-RRM (D. Del. 1998), Judge McKelvie found the following language to meet the requirement:

> [t]he [patent in suit] is invalid and unenforceable because it fails to satisfy the requirements contained in 35 U.S.C. §§ 41 and 101 et. seq., including but not limited to, §§ 102, 103, and 112. (Exh. C).

This Court rejected the plaintiff's argument that it could not prepare its case without a better understanding of defendant's defenses and counterclaim, stating that "the appropriate means for

achieving this understanding is discovery" and that plaintiff should "utilize the appropriate discovery strategies permitted by the Federal Rules." McKesson should follow the same course.

Similarly, in another case, this Court found that an invalidity defense that merely stated the patent was invalid under several sections of Title 35, U.S.C., was sufficiently pled and provided the plaintiff with fair notice of the nature of the defense. *CFMT*, 1996 U.S. Dist. LEXIS at *9-10 (emphasizing that "this Court has held that pleading invalidity in such general terms satisfies the requirements of notice pleading"). Courts in other districts have done the same. *See, e.g., Pittway Corp. v. Fyrnetics, Inc.*, 1992 U.S. Dist. LEXIS 12172, *16, 18 (N.D. Ill. 1992) (finding that the defendant satisfied the notice pleading standard even where, as plaintiff noted, the invalidity counterclaim "raise[d] virtually every possible legal reason generally available to attack a patent"); *Bob's Space Racers, Inc. v. Hampton Co.*, 1996 U.S. Dist. LEXIS 17668, *4, 6 (M.D. Fl. 1996).

McKesson fails to cite any Federal Circuit or District of Delaware case to support its position. Instead, McKesson cites a single decision from the Northern District of California, *Advanced Cardiovascular Systems, Inc. v. Medtronic Inc.*, 41 USPQ2d 1770 (N.D. Cal. 1996). Ironically, that case suggests that less specificity is required for an invalidity defense where the plaintiff itself has failed to specify which of the patent's claims are allegedly infringed. *Id.* at *8. As explained above, this is precisely the situation here, because McKesson's complaint fails to identify which claims of the '164 patent it is asserting, or even the name of the TriZetto "system" that is accused of infringement. (D.I. 7 ¶ 6).

McKesson's motion to strike TriZetto's second affirmative defense should be denied.

IV. TRIZETTO'S SIXTH AFFIRMATIVE DEFENSE IS ADEQUATELY PLED

TriZetto's Sixth Affirmative Defense states that:

> The '164 patent is unenforceable because the Plaintiff comes into Court with unclean hands. Plaintiff has committed patent misuse by attempting to enforce a patent it should reasonably know is invalid and not infringed. (D.I. 10, ¶ 15).

It is well-established that the bringing of a patent infringement suit knowing that the patent is invalid or unenforceable can constitute patent misuse. *See, e.g., Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979); *Arcade, Inc. v. Minn. Mining & Mfg. Co.*, 1991 U.S. Dist. LEXIS 19768, *48 (E.D. Tenn. 1991) ("Patent misuse occurs when a patentee enforces its patent knowing that it is either invalid or unenforceable."). Although McKesson correctly states that an allegation of bad faith is required to assert a patent misuse defense based on a patentee's bringing of a patent infringement suit, its motion to strike TriZetto's Sixth Affirmative Defense should be denied because TriZetto has sufficiently alleged such bad faith by McKesson.

To make a sufficient allegation of bad faith to support a defense of patent misuse, an alleged infringer is not required to explicitly use the phrase "bad faith" in its pleading. Rather, an affirmative defense that alleges the act constituting the bad faith, *i.e.*, knowingly bringing suit to enforce an invalid or unenforceable patent, is sufficient. As the Ninth Circuit held, for example:

> All that is required for a finding of bad faith in the context of an infringement suit is that the patent holder...knew that its patent was invalid. The bad faith involved -- attempting to enforce a government granted monopoly to which the patent holder knows he has no right -- is as much extrinsic to the suit as it is inherent in

filing a legal cause of action devoid of merit. *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1289 (9th Cir. 1984).[3]

Because the act of bringing a patent infringement suit with knowledge that the patent is invalid itself constitutes bad faith, and TriZetto has alleged that McKesson engaged in this act, TriZetto has adequately pled bad faith in support of its patent misuse defense.[4]

TriZetto has also sufficiently alleged an anticompetitive purpose in its Sixth Affirmative Defense. The Federal Circuit has explained that an improper purpose exists whenever a patentee's goal in bringing suit is "not to win a favorable judgment," but to engage in the litigation process itself, "regardless of the outcome." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995). Although McKesson ostensibly brought this suit to enforce its patent, in reality its purpose could not have been to obtain a favorable result because it knew or should have known that its patent was invalid and unenforceable. Moreover, McKesson brought this lawsuit only after the parties had engaged in years of unsuccessful negotiations regarding a possible business alliance. Thus, the purpose and effect of this lawsuit are inherently anticompetitive because McKesson's only purpose in bringing suit could have been to interfere with the business of its competitor, TriZetto. *See Cummins-Allison Corp. v. Glory Ltd.*, 2003 U.S. Dist. LEXIS 16454, *5 (N.D. Ill. 2003) (finding

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[3] Although the *Handgards* court made this statement in the context of an antitrust claim, "courts have determined that the treatment of the bad faith issue in the patent misuse context is largely the same as in antitrust law." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 706 F. Supp. 94, 105 (D. Mass. 1989).

[4] The fact that TriZetto alleges that McKesson "should reasonably know" that its patent is invalid, rather than that McKesson knew that its patent is invalid, does not affect the sufficiency of its pleading. *See, e.g., Hoffmann-La Roche, Inc. v. Genpharm, Inc.*, 50 F. Supp. 2d 367, 379 (D.N.J. 1999) (holding that a defendant sufficiently stated a claim for patent misuse where it "alleged that plaintiffs initiated a baseless suit to enforce...patents which they knew or should have known were not infringed for anticompetitive purposes") (emphasis added).

that a counterclaim of patent misuse was properly pled since it alleged that the patentee "did not bring the infringement suit...to enforce a patent right, but instead brought the suit knowing there was no infringement in an attempt to gain anticompetitive strength").

Finally, McKesson's reliance on *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 2004 U.S. Dist. LEXIS 16584 (S.D.N.Y. Aug. 19, 2004), is misplaced. In *Takeda*, the defendants failed to allege even general facts to support their claim of misuse and, instead, "merely parrot[ed] the elements" of such a claim. In contrast, TriZetto has alleged facts that show bad faith and an anticompetitive effect, *e.g.*, that McKesson brought its infringement suit when it should have known that its patent was invalid and unenforceable. Other courts have recognized similar factual allegations as sufficient to support a claim of patent misuse. *See Honeywell Consumer Prods., Inc. v. Windmere Corp.*, 993 F. Supp. 22, 23-24 (D. Mass. 1998) (finding that a patent misuse defense was adequately pled where the defendant alleged that the plaintiff "brought this suit knowing or believing that its patent is invalid, unenforceable and/or not infringed").

Thus, the Court should deny McKesson's motion to strike because TriZetto has adequately pled its patent misuse defense.

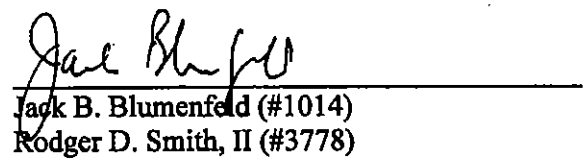
V. DISMISSAL IS INAPPROPRIATE

In the event that the Court should find that any of TriZetto's defenses have not been pled adequately, the appropriate remedy is to grant leave to amend. Leave to amend should be "freely given when justice so requires." *Fiala v. Blank & Co.*, 2003 U.S. Dist. LEXIS 2609, *21-22 (W.D. Tenn. 2003). TriZetto has demonstrated that a substantial body of evidence exists supporting its defenses and counterclaims. TriZetto should be given the opportunity to explore and develop its contentions during discovery.

CONCLUSION

For the reasons stated herein, McKesson's motion should be denied.

MORRIS, NICHOLS, ARSHT & TUNNELL



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December 7, 2004

EXHIBIT A

Harvard Business School

9-394-204
Rev. February 5, 1999

Marcia Radosevich and Health Payment Review: 1989 (A)

Marcia Radosevich, president of Health Payment Review (HPR), wondered what it would take to convert prospects into customers.

Marcia and several health care experts had launched HPR in 1987 to develop and market software that would review reimbursement claims submitted by doctors, hospitals, and laboratories. HPR management believed that reviewing claims for overcharges and inconsistencies could result in significant savings for providers of health plans such as HMOs, insurance companies, and corporations. Payments for surgical procedures, for example, could be reduced by 5% to 15%. And, using software would be far less costly than manually inspecting claims.

With $750,000 provided by the Caterpillar company, a leading manufacturer of earth-moving equipment, HPR had begun developing its first product, *CodeReview*. Two years later, in 1989, it had developed a prototype that ran on personal computers (PCs) and that it hoped to convert to a mainframe-based product. The company had nearly exhausted its cash, however, and Marcia decided to sell the PC version in order to fund development of the mainframe product. By March, her sales efforts had come to naught: many potential customers had shown great interest, but none had given HPR an order.

Background

Marcia, the third of six children, was born and raised in Iowa. Her father had died when she was 13. In 1974, after graduating with a sociology degree from Cornell College in Iowa, she worked as legal secretary and paralegal. After nine months, she decided against a legal career and entered graduate school at the University of Iowa. A Ph.D. in sociology in 1982 led her to faculty positions at Boston College and Yale, where she studied social deviance and white-collar crime. Marcia found her research enjoyable, but not her teaching assignments and, in 1984, decided on another career change. She ruled out law and government, where she feared the excessive bureaucracy and red tape, and although she felt that business was where "dumb people went," she enrolled in Wharton Business School's summer program. The program, which limited enrollment to 40 and compressed an academic year's worth of courses into a summer term, attracted many other "refugees from the world of academia."

Professor Amar Bhidé and Brian Mohan, MBA '84, prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

Her certificate in Business Administration and fascination for quantitative analysis and research led Marcia to a job with a premier health care consulting firm. There she managed high-visibility projects with Chrysler, General Motors, and the UAW, developing expertise in analyzing health care costs as well as in compiling and interpreting clinical and statistical data.

Marcia left the consulting firm in 1988. She recalled:

> It was a tremendous organization with outstanding people. But I still felt stifled by the research. It was too academic and we didn't have the power to implement real change. I wanted to make things happen.

In her next job, as regional director for Managed Health Care Services (MHCS), Marcia developed and managed a preferred provider organization (PPO) for the Travelers Insurance Companies. She enjoyed her experience at MHCS:

> I used my skills to create something—putting together hospital and physician PPO deals. I could make things happen, even when others said it was impossible: I developed networks, which were among the fastest growing in the country, in markets that skeptics in the company said were saturated. And, I learned how to sell and negotiate from the two principals of the firm. They were the best teachers I've ever had.
>
> I had imagined salespeople to be slick, fast talking, amusing persons. I had imagined negotiating was pounding your shoe on the table. These guys taught me that selling is about building a relationship. It's about getting in early, defining the playing ground and the rules of the game, creating a sense of urgency, and building toward a conclusion. It's about being nonthreatening: "Go ahead and think I'm some nice girl from Iowa, and I'm a Ph.D., and I would never be threatening to anyone." It's about patience, it's about controlling the timing.
>
> These guys never raised their voices. They were smart, unassuming, and their egos didn't get in the way. They let somebody else take credit for their ideas. They spent all the time they needed to—morning, noon and night—being available. Clients would sometimes say to them, "Here's the language I want in the contract" and it would be totally unacceptable. They'd never say "No"; they'd say "let me understand what your concern is here. What's the problem you are trying to solve with this language?" Then they'd find out that you didn't really want their first-born child.

When a large company acquired MHCS, in 1988, Marcia prepared to take a six-month sabbatical and go scuba diving. Instead, the HPR opportunity came along.

Launching Health Payment Review

HPR began as a joint research project between Boston University (BU) and Caterpillar, Inc. headquartered in Peoria, Illinois. For many years, Dr. Robert Hertenstein, medical director of Group Insurance at Caterpillar, had reviewed reimbursement claims manually for accidental or intentional errors and saved the company about $500,000-$600,000 a year. For example, Hertenstein often found "unbundling" claim errors billing separately for the components of a treatment instead of for a less expensive inclusive procedure. Thus he would look for doctors who submitted an "a la carte" bill of $4,500 for the components of a hysterectomy rather than the $2,400 bundled flat fee.

Concerned about its growing health care claims and its reliance on the skills of one individual, Caterpillar sought the help of BU's Health Policy Institute (HPI). The HPI team working on the Caterpillar project—Drs. Richard Egdahl, George Goldberg, and William Ryker—were well-known researchers in health care cost containment who also had extensive clinical experience. In the course of their study, the team concluded that an automated system to review claims would produce considerable savings for organizations such as Caterpillar. And, they decided to form a private, for-profit company to develop and sell such systems.

Marcia got involved with the HPI team as a result of her friendship with Goldberg, whom she had worked with in her previous consulting job. For about six months, before HPR was formally launched, she served as a consultant to the HPI doctors. In this capacity, she urged them to seek financing from Caterpillar and helped negotiate the terms. Then, in July 1988, the doctors appointed Marcia president.

> They needed a businessperson, and as far as they were concerned, I was a business genius! These men were brilliant researchers and academics, but they were completely without a clue on all aspects of the business. I had been out of academia for four years at the time, and they thought I was very experienced. I was immensely attracted to the concept. I liken the product to a paper clip or the Post-It note pads. I couldn't believe that no one else had developed software to review claims. It was such a simple and ho-hum idea—and yet an incredible amount of money could be made.

Although by June, Caterpillar had agreed, in principle, to provide $750,000 in return for a royalty on HPR's product, the parties had not signed a contract. Marcia recalled:

> When I walked in the door, it was through an academic BU appointment at HPI. There was no money in HPR, just these incomplete agreements, with brackets around paragraphs for the incomplete stuff. My first job was to try to do this deal. I was being paid an academic salary, with the proviso that as soon as I got the money from Caterpillar I could go back to a quasi-normal private-sector level. So I was highly motivated.
>
> I knew the negotiations could go on forever. They had been going on forever. Nobody knew what they were doing. The guy at Caterpillar who was trying to do it was the benefits manager, and the guy at HPI was a Ph.D. in Operations Research. They would talk on the phone, and then two weeks would go by before they had another discussion. Every time somebody would change something, they would give it back to the lawyers to have them completely redraft the whole thing.
>
> We had to create a sense of urgency. The first day I walked in, I called the guy at Caterpillar and said, "We have to get this done within 30 days, or else I'm going to shop it. I'm not getting paid, and there are other people interested in this. Just do it or not." He tried to tell me that Caterpillar goes on vacation in August. I said, "No, this has all got to be done by then."
>
> We ended up signing in six weeks. I worked night and day. I was calling this guy at home. I was faxing things to him. I was courier-ing things to him at home. He never had this done to him before. He kept wanting to wait until next week. I said, "No." I was driving everybody crazy. He said, his lawyers couldn't turn documents around that fast. I asked him for the names of the lawyers. I would call them: "Please do this for me. I'm desperate, I'm not getting paid, we've got to get this done." I think that's one of the many areas where being a woman really helped

me, because they perceived me as much less threatening. This was all I did morning, noon, and night. I wrote stuff, and I would try to keep lawyers out of it as much as I could. I had this Ph.D. in operations research writing things. He said, "Marcia, I'm not a lawyer." I said, "It doesn't matter. Write it up, write it in English." Then we gave it to HPR's lawyer and I told him, "You have to write this up immediately." He was a BU patent attorney who said he wasn't a corporate lawyer. And I said, "William give me this . . . just write it up." He had a couple of percentage points of HPR because he had incorporated the company. I said, "You've got to earn your money here. Come on, I'm going to make you rich." So he worked late weekends, and he wrote this agreement up. It's far from being a perfect legal document, but it was legal; it was enough, and they signed it. (See Exhibit 1 for excerpts from the Caterpillar agreement).

Caterpillar agreed to put up $750,000 in three equal installments. At the very beginning, they had said, "Rather than give you the money, we'll just develop the software ourselves." We asked, "How much would it cost you?" They said $750,000. We agreed to do it for them for $750,000, and we promised to throw in on-going maintenance and support for free. We knew that $750,000 wasn't enough, but it would get us through the first 6 to 12 months, and we could get a PC version done. We would need more money for a mainframe version, but we would cross that bridge when we got there.

The deal could have been structured in a variety of ways. The most obvious way was for Caterpillar to take a large equity position. That I badly did not want. I didn't want a big company as a partner. They would want to try to run everything. They wouldn't understand the business I was in: They build earth-moving equipment; they don't build software. I was hoping to grow the company and take it public; but big-company partners that don't need you to make a lot of money are less likely to let you do the kinds of things that you need to do in order to get rich. Big companies often use little companies as a think tank or an R&D extension.

We tried to figure out a deal that would give Caterpillar some upside potential, and then when I was still a consultant, we came up with the idea of a royalty stream. Then William Ryker wrote it up—he has to write up everything—and I reviewed and edited it. He then just wanted to send it to the Caterpillar guy, but I made William call first and read it over the phone and then follow up in writing. We went through many iterations, with William writing quite elaborate equations for the royalty, which amounted to about 5% of net and 1% of gross. I wonder if the Caterpillar people really understood William's equations--I don't think our chairman, Dick Egdahl, who is brilliant, understood. But, by the time I joined HPR full time, they had agreed to the formula. William is very sincere, and we were able to show them how much money they would make, if we were successful, without all the hassles of equity.

Then the problem became that they wanted an open-ended royalty stream. But deals are good only if you can get out of them. I didn't want this ongoing obligation to Caterpillar; one of these days, we would go public, and I didn't want to write in my prospectus that I owed Caterpillar 1% of the gross revenues of my flagship product. At first, it seemed unfair, to them, but we eventually obtained an option to buy them out, according to a formula we negotiated. They didn't want us to be able to buy them out, but they understood, from a business perspective, why it made sense.

They began wanting to postpone final agreement on the buyout provision, and I wouldn't let them. I knew if we got the deal signed, if we got the money, and if they got their software, we were never going to agree on how I could buy them out early. So I told them to sign the entire deal, or I would shop it somewhere else. I told them Aetna would give me money. And I gave them all the reasons why I would not buy them out early, while I was getting them to tell me that I could. They finally just agreed. Part of it was creating the momentum and the sense of urgency. It had to be done by the end of August, or I would go elsewhere. I had to get paid. Part of it was forcing them to agree to all of it at once. And finally, we just outlasted them. They had been in negotiations at this point almost a year. They just wanted to get it over with and get on with doing the work.

We also gave a little bit of equity in HPR to BU's venture capital fund. Our chairman, Dick Egdahl, wanted to create a model whereby for-profit enterprises could be spun out of universities, where the university would not be a stone around the entrepreneur's neck, yet would have some recognition and upside. We didn't use any of BU's money; still, the fact is that the Caterpillar relationship came about as a result of the university. And by giving a little bit of equity, we got a lot of attention from the BU people. They felt great: they hadn't given us any money, and they got equity.

March 1989

With Caterpillar's money in hand, HPR began developing *CodeReview*, which belonged to the category of software known as expert systems. Expert-systems software helped users in fields such as oil exploration, process control, and medical diagnosis solve difficult problems by incorporating the rules of thumb of experienced practitioners. Similarly, HPR planned to draw upon the knowledge of more than 50 experienced physicians, surgeons, and subspecialists and include tens of thousands of clinical-decision rules in *CodeReview*. It would update this knowledge base annually, as procedures and their payment schedules changed.

The company planned to develop a PC-based prototype and then a version for mainframe computers. HPR programmers could develop the PC prototype relatively quickly using D-Base, a popular off-the-shelf database package. Caterpillar would use this version immediately, as a substitute for its manual reviews. The prototype would not, however, process large numbers of claims quickly. Moreover, because most organizations processed their medical claims on mainframes, they would have to enter data twice—on the PC for review and then for normal processing. Therefore, HPR planned to follow the PC-based prototype with a mainframe version. But developing the mainframe version would be more time consuming and difficult. HPR wanted a program that could easily be adapted to many types of mainframes and, unlike the PC version, could not build on an off-the-shelf package like D-base.

In accordance with its plan, in 1989, HPR delivered a PC product to Caterpillar on January 2. It covered, Marcia said, "just the surgical section, but it was enough to call it a product, and it was all Caterpillar wanted at the time." Soon thereafter she decided to try to sell the PC prototype to other customers, before HPR had developed the mainframe version. Marcia recalled:

Rule 101 in software development is: you never sell the prototype. But, we were running out of money, because William Ryker, who's brilliant, decided he wanted to be vice president for software development. He went to the BU bookstore, bought a book on expert systems, and decided how to build the system. And he's been giving much of the money we got from Caterpillar over to two computer consultants who aren't building anything useful. They live in Iowa so that they can meditate with the Maharishi Yogi there. I've been sweating bullets. It's like an

hourglass; every drop of sand is another dollar. But, William is a founder of the company . . .

We have monthly expenses of $85,000. We now have on staff three full-time employees and five full-time consultants—two programmers (the two in Iowa), two product developers—who generate the coding rules—and one salesperson who is an MD.

I thought, we're going to go bankrupt. I looked around for things to sell, and the only thing we can sell is the prototype. I thought, "Screw the rules, we've got to sell this PC thing, even if it wasn't built as a commercial system." We hired a consultant to do some technical writing and the documentation to make it look like a product, and we started trying to sell it. We drew up a licensing agreement — $100,000 for installation and $60,000 for annual maintenance and updates of the knowledge base.

There are a lot of people in the industry who know me or Dick Egdahl, so it wasn't any problem getting an audience. Dick also lent us the services of Steve, a young M.D. at the Health Policy Institute who wanted to learn how to sell. Steve and I visited several dozen potential customers.

We've really worked at building relationships with prospects. To build a relationship, you have to spend time with someone. You have to have face time, and you have to spend money on airfares to get it. And you send them little articles to keep your name visible: "I saw this article in the *Wall Street Journal*; you might be interested." Of course, the guy has seen the article, but you thought of him and talked it over with him. That helps a lot. So I've been working to get as much face time as I can, and I've been coaching Steve as well.

Steve, who has a great personality, can play the doctor bit up to the hilt. He tells them war stories about working in the Emergency Room, and they feel that they were in there, too, and that maybe they are as smart as Steve. Dick Egdahl says that most people don't get five minutes with their doctor, and now here's Steve lavishing attention on them. And when benefits managers deal with doctors or Ph.D.s, it makes them more comfortable: We are not salespeople; we are not even businesspeople. We are intellectuals, right?

But, we haven't made a sale yet. We've encountered great skepticism. *CodeReview* runs only on PCs, and many of the guys we've talked to run big mainframe shops and have severe mainframitis. Nobody has done anything like this before, and they're afraid that doctors will react negatively to reviewing claims. The payers of health care still have a lot of doctor fear. It's OK for Caterpillar, they say, because they own Peoria. HPR is a brand-new company—what if they use it, make it an integral part of their operations, and then HPR sinks? They have a million reasons not to do it. I actually think a number of them are interested, but they're afraid to be the first ones.

And we have only a couple of weeks' worth of cash left. Beyond that, I suppose we could ask BU's venture capital fund for a short-term loan. Dick Egdahl also has some grants at the HPI, and we could put some more people on the Institute payroll and pay the Institute back when we get some revenues. But that can only be a stopgap.

We have to make a sale.

Exhibit 1 Excerpts from License Agreement with Caterpillar Inc.

Background

HPR is a start-up company which intends to develop and market a computer software product which, in general, is useful in applying medical judgment to the evaluation of medical claims submitted by health care practitioners prior to payment of such claims.

CATERPILLAR desires to facilitate the development of such computer software product and to use the product at any of its facilities or the facilities of its subsidiaries, wherever located.

Section 2.1

HPR shall initially develop a microcomputer version of the SOFTWARE to run on IBM AT or PS/2, or compatible hardware, with 640k RAM and 10mb hard disk drive, and deliver the same to CATERPILLAR for acceptance testing.....

Section 2.4

After completion of said microcomputer version above, HPR shall develop a version of the SOFTWARE that will interface with CATERPILLAR's mainframe computer claims processing system in a language mutually agreed upon by the parties and deliver a prototype version of the same to CATERPILLAR within 6 months of the completion of said microcomputer version.....

Section 2.5

To assist HPR in the development of the SOFTWARE and as additional consideration of the rights herein granted to CATERPILLAR, CATERPILLAR agrees to provide, at no charge, the services of Robert D. Hertenstein, M.D. to serve as a consultant to HPR.

Section 4.1

Upon acceptance as herein provided, HPR shall grant to CATERPILLAR a non-exclusive, non-transferable and perpetual CORPORATE LICENSE to use the OBJECT CODE of the SOFTWARE, as provided herein.....

Section 5.1

For the rights to be granted to CATERPILLAR, CATERPILLAR shall pay HPR a total sum of Three Hundred Thousand Dollars ($300,000.00).....

Section 11.1

For a period of twenty (20) years from the date of this Agreement, HPR shall provide MAINTENANCE SERVICE to CATERPILLAR....to the extent that it is made available to HPR's other customers. Such MAINTENANCE SERVICE shall include, but is not limited to:

One copy of each UPDATE to the SOFTWARE and SOURCE CODE at the time of its release.

Reasonable written or telephone consultations regarding use of or problems with the SOFTWARE.....

Excerpts from Loan Agreement:

Section 2.01

.....to make a loan in the principal amount of Four Hundred Fifty Thousand Dollars ($450,000.00) (the "Loan") to the Borrower in three equal installments as follows:

1. One Hundred Fifty Thousand Dollars ($150,000.00) within 20 days after Lender's acceptance (as such term is used in the License Agreement) of the first prototype version.

2. One Hundred Fifty Thousand Dollars ($150,000.00) within 20 days after Lender's acceptance of the second prototype version.

3. One Hundred Fifty Thousand Dollars ($150,000.00) within 20 days after Lender's acceptance of the third prototype version.

Section 2.02

(a) REPAYMENT. Borrower shall repay said Four Hundred Fifty Thousand Dollars ($450,000.00) plus interest thereon by making the following two types of payments to Lender:

(1) Borrower shall pay Lender an amount equal to five percent (5%) of Borrower's gross sales from the date of this Agreement, until an amount equal to Seven Hundred Fifty Thousand Dollars ($750,000.00) has been paid to Lender. If, however, an amount equal to $750,000.00 has not been paid to Lender as of December 31, 1993, on that date Borrower shall pay that portion of said $750,000.00 which has not been previously been paid.

(2) Immediately following the payment of the foregoing Seven Hundred Fifty Thousand Dollars ($750,000.00), Borrower shall pay Lender for a period of twenty years (measured from the date of the final installment on such $750,000.00 payment) less the number of years for which it takes Lender to repay said $750,000.00, the greater of 1% of gross sales for each fiscal year or 5% of net after-tax profit for each fiscal year.....

(b) *SALE OF STOCK.* In the event that a majority of the issued stock of Borrower is, in a single transaction, either a) sold to a third party not presently a stockholder.....

.....In the event that a sale is made prior to full payment by the Borrower of the $750,000.00 due under Section 2.02 (a) (1), or, made after such payment but prior to two full calendar years of Section 2.02 (a) (2) payments, the amount to be paid to the Lender shall equal a) any remaining amount due under Section 2.02 (a) (1), plus b) the average of the amounts which were paid by the Borrower under Section 2.02 (a) (2), or would have been paid by Borrower under such Section had the amount in 2.02 (a) (1) previously been paid, for the two full calendar years preceding the sale, multiplied by the number of years remaining under the Section 2.02 (a) (2) payment obligation.

Harvard Business School

9-394-205
Rev. August 10, 1998

Marcia Radosevich and Health Payment Review: 1989 (B)

Marcia recalled:

We were within a week of having to shut the doors when I thought of the classic puppy dog sale. The product was great. It had a cute interface. When you saw it and started using it and saving money, I knew it would be like heroin. You couldn't do without it. But people were afraid to make a commitment and look like a fool. So I thought, "Let's take away the risk."

We'd offer prospects a PC with our software loaded on it. They wouldn't have to pay us anything except 50% of anything they saved.

Professor Amar Bhidé and Brian Mahan, MBA '94, prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

Harvard Business School

9-394-206
Rev. August 10, 1998

Marcia Radosevich and Health Payment Review: 1989 (C)

Marcia continued:

We made a list of the people who we thought were the most intrigued, but were afraid, and who fit a number of characteristics: They could make the decision themselves—sometimes our primary contact was the medical director who couldn't make this kind of a decision. We needed a vice president for claims—which is where the software would be used—who was in a small-enough company or who had a large-enough responsibility to do this kind of experiment, and who was on the verge of saying yes.

About a dozen or so of the people on our list turned us down.

Perry, who worked at the Globe Insurance Company in Milwaukee, was next. He had signing authority, and although he, too, had been unwilling to sign a license agreement, he seemed to want the software.

Steve, our doctor who was trying to learn how to become a salesperson, had established a relationship with Perry. Steve and I had made the first sales call together, but then Steve made several trips to Milwaukee by himself. Perry was a vice president in a small insurance company and loved the fact that this smart surgeon was his friend.

So I told Steve, "Call up Perry, tell him you're going to be in Milwaukee and you'd like to stop by." Steve said, "That's a lie." I said, "It's not a lie; I'm sending you to Milwaukee. When you get to Perry's office, you drop off a little PC and say he can just use our software for three months and he doesn't have to pay us anything except half of what he saves."

Professor Amar Bhidé and Brian Moham MBA '94, prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

Harvard Business School

9-394-207
Rev. August 11, 1998

Marcia Radosevich and Health Payment Review: 1989 (D)

Marcia continued:

Although I had met Perry and done the initial presentation to him, I didn't go along because his relationship was with Steve. If I had gone out with Steve, there would have been a change in the pattern: it had always been Steve on the phone, Steve taking Perry out to dinner. If I had gone, it might have caused Perry to think, "Oh, this is a deal."

I wanted to make it casual, sort of an afterthought: "I'm in Milwaukee; I'll stop by." Perry was afraid to make a commitment, and we made it so there was none. Steve was not climbing into an airplane specifically to see him. This was just his buddy Steve, in town for some reason—God knows why.

Steve didn't even ask Perry to sign a piece of paper. To address Perry's concerns about doctor reaction, Steve said that if he had to, he would move in and personally answer to physicians on the phone. That's where Steve being a doctor came in handy. We took care of the risk.

We then called a couple of other people with the same offer, but they wanted to wait to see what Perry's experience would be like.

I suspended the consultants who were writing our mainframe software, and we waited. In a couple of weeks, Perry called and said he wanted out of the deal. He already owed me $60,000 from the $120,000 he had saved for Globe Insurance. He wanted to go back to the original $100,000 license with the annual $60,000 maintenance fee. Could we mail him the license? I said to Steve, "You don't mail it. You get out there, sign the deal, and tell him he has to give us a check when he signs."

Professor Amar Bhidé and Brian Mahun, MBA '94, prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

Harvard Business School

9-394-208
Rev. August 11, 1998

Marcia Radosevich and Health Payment Review: 1989 (E)

Marcia continued:

We then called a sister company of Globe Insurance who had been waiting to see what Perry's experience would be. We offered to share their savings as well, but they went directly to the license.

Then we started calling everybody. We thought we had to have a name for it, so we called it a pilot study. I wrote a simple one- and one-half-page agreement, with no legalese. I didn't want it to sound like a lawyer had written it, although I had our lawyers look at it to make sure I wasn't getting into trouble. We offered prospects the option of splitting the savings or paying us $5,000 a month—anybody can afford $5,000 a month. In some cases, we even let them test it for free, but I always wanted to try and get money, because then people would value the trial. At the end of the pilot, customers could convert to a full license. We sold a zillion of these, and most converted, but we looked forward to the day when we were well enough established so that we wouldn't have to go through these pilots.

Professor Amar Bhidé and Brian Mahan, MBA '94 prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

Harvard Business School

9-394-209
Rev. August 11, 1998

Marcia Radosevich and Health Payment Review: 1989 (F)

The summer of 1989 found Marcia in Fort Wayne, Indiana, trying to presell the mainframe version of *CodeReview* to an insurance company client. She recalled:

> After we sold our pilots, we began work on the mainframe version.
>
> Our design is quite clever. Business applications on mainframes have traditionally been written in a programming language called COBOL. Our software is being written—behind schedule and over budget by William's meditators in Iowa—in a language called C. It will run on several types of hardware "servers." These servers will be connected to but outside the mainframe, because we need to update our knowledge bases frequently, and we don't want to bring the whole system down while we do it. Besides, adding servers is much cheaper than adding more mainframe capacity.
>
> I've been trying to sell this concept all over the country, and I've just been laughed at. This is an industry that is hooked on 1970s' technology. When I use words like servers, C, and Unix, they act like I am a communist, feminist radical from Boston.
>
> So now I'm in Fort Wayne, Indiana, talking to the systems guy of an insurance company. He's a great big guy, with a great big brass belt buckle. I'm standing at a board, like a professor, doing price-performance charts, trying to convince him this is the cheapest way: you don't have to buy more iron, and you don't have to hire more people. This great big guy hitches up his belt buckle, slams his hand down on the table, and says, "Little lady." I look at him, and he says, "I run me a COBOL shop and got me a bank of 3090 mainframes, and I got me an army of COBOL programmers. Don't give me this C s__t."

Professor Amar Bhidé and Brian Mahan, MBA '98, prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

Harvard Business School

9-394-210
Rev. August 11, 1998

Marcia Radosevich and Health Payment Review: 1989 (G)

Marcia continued:

It was summer. It was hot. I had had it. I looked at him and said, "If I give this to you in COBOL to reside on your mainframe, would you buy it?" He said, "Yes." I said "Done." We signed a deal. We would give him a PC version as an interim measure until we got to the mainframe.

I now came home to Boston and wondered, "What are we going to do?" We had to architect an affordable, flexible, and maintainable COBOL product that would reside on a host without having to rewrite it for every different database manager and every different telecommunication system. It took a little while to get there, but we finally hit upon it, and then it all seemed easy and natural.

It actually is a very simple program. It only has about 6,000 lines of code. Quite a number of times big companies say, "I have me an army of COBOL programmers; I don't need you." I say to them, "Fine, I will give you the software for free. You just pay me for my knowledge base, and it changes every year because the codes change. There is a built-in obsolescence in 12 months. When I put it to them that way, then they begin to see that the value isn't really in the software; it's in the knowledge base.

Professor Amar Bhidé and Brian Mohan, MBA '94, prepared this case as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

EXHIBIT B

An Access-oriented Negotiated Fee Schedule

The Caterpillar Experience

RICHARD H. EGDAHL, M.D. and ROBERT D. HERTENSTEIN, M.D.

This paper describes the system used by Caterpillar Corporation (CAT) in Peoria, Illinois, to reimburse surgeons. The CAT system assures access for Caterpillar employees and their families to a selection of qualified surgeons, while achieving cost savings through improvements in processing of surgical claims and negotiation of selected fees. CPT-4 codes are recoded for greater accuracy, when indicated, surgical services that have been incorrectly unbundled are rebundled, and the appropriateness of surgical assistant charges is reviewed. A "degree of difficulty" relative value scale (DODRVS) of surgical services is periodically revised as technology changes. The DODRVS multiplied by a regional factor, determined by local market research, establishes the fee that CAT will pay the surgeon. Balance billing is permitted if the patient (1) is informed in advance by the surgeon that the fee will be higher than CAT will pay, and (2) knows that the service can be obtained from other local surgeons who will accept the CAT fee. The goal of the CAT method of surgeon reimbursement is to gain physician support for an access-oriented, market-driven negotiated fee schedule. Compared with a resource-based relative value scale (RBRVS) methodology, the CAT system is not formula-driven and depends on physician acceptance.

FOR MORE THAN 25 years, physicians have benefited from a generous fee-for-service system of payment. However, between 1965 and 1985, national expenditures for physicians' services have increased almost tenfold, from $8.5 billion in 1965 to $82.8 billion in 1985.[1] As a result, several possible physician payment reforms are being considered. Prospective payment by diagnostic-related groups (DRGs), put in place to control Medicare hospital expenditures, is a fact of life for hospitals. Medicare and Medicaid are now pushing for changes in the way they pay physicians. Managed care programs are negotiating discounts from all types of health care providers.

Presented at the 107th Annual Meeting of The American Surgical Association, Palm Beach, Florida, April 21–23, 1987.

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From the Department of Surgery and Health Policy Institute, Boston University Medical Center, Boston, Massachusetts, and Caterpillar Corporation, Peoria, Illinois

Reform activity can be identified on many fronts: (1) Congress has frozen Medicare fees, effective June 1984 through January 1987. Congress' intent is now to shift the burden of effectively constraining the growth of Medicare Part B costs to providers rather than Medicare beneficiaries. (2) The Physician Payment Review Commission, created by Congress, has issued a recent major report, outlining ways that physicians could be reimbursed under Medicare in the future.[2] (3) In fall 1985, the Health Care Financing Administration (HCFA) contracted with Harvard University to conduct a 30-month study of resource-based relative value scales (RBRVS) for physician services.[3] This system is being developed under the direction of William Hsiao, Ph.D., Harvard School of Public Health. The American Medical Association is a subcontractor on the study for HCFA. The study is scheduled to be completed in July 1988. (4) The Massachusetts Rate Setting Commission is revising its Medicaid fee schedule, based on the RBRVS, for planned application in mid-1987. (5) The Massachusetts Insurance Commissioner asked Blue Shield to consider reforms in physician payment, with an emphasis on developing an RBRVS, as a condition of his approving a Blue Shield rate increase in 1987. (6) Congressional hearings on physician fee schedules continue, and congressionally sponsored studies of physician fees have recently been published.[4,5]

Within the administration in Washington, proponents of physician fee reform are calling for an expanded use of capitation in the long term, or some form of physician DRGs.[6] But these changes are not imminent. During the next several years, fee payment modifications will be based in fee-for-service recalculations. If the revised physician fee schedules achieve acceptable levels

TABLE 1. *Medicare Prevailing Fees ($, 1984)**

State	CABG	Appendectomy	Cataract
New York	6000	1134	1547
Michigan	3100	399	825
Rhode Island	2587	516	928

* The charges indicated are for specialists and for the large urban areas within the states listed.

From the U.S. Department of Health and Human Services, Health Care Financing Administration. Medicare Directory of Prevailing Charges 1984. Washington DC: U.S. Government Printing Office, 1984.

of patient access and physician support, they will be part of the blueprint for future health care delivery in both private and public arenas.

Background

Medicare's "customary, prevailing, and reasonable" (CPR) payment system is, by general consensus, unsatisfactory in today's competitive market in health services. There are many problems associated with CPR. It tends to be inflationary and slow to respond to alternatives in technology and changes in both availability of physicians and need for services. Some charges appear excessive to most observers, even taking into account geographic cost-of-living variations and other variables. For example, under Medicare, the cost of a triple vessel CABG (coronary artery bypass graft) in New York in 1984 was $5500. The cost of this same procedure in Michigan was $3100 and $2587 in Rhode Island (Table 1).

Similar variations are found in fees from the private sector. For example, unexplained fee variations exist in managed health care models such as independent practice associations (IPAs). Hip replacement at three different IPAs in the eastern part of the country ranged from $2808 to $4274 (see Table 2).

Noting these wide discrepancies, the federal government and a number of large private purchasers of health services have turned their attention to the ways physicians are compensated for the care they provide. Fundamental changes in the methodology of physician reimbursement are being discussed. Serious consideration is being given to systems that would pay physicians by capitation or by including the physician payment with the hospital DRG payment. However, both options represent a radical departure from the current system and are viewed as politically unrealistic, at least in the short term.

TABLE 2. *Fee Variations in 3 IPAs, 1986 Fees ($)**

Operation	Plan #1	Plan #2	Plan #3
Appendectomy	645	950	1111
Cholecystectomy	1055	1465	1710
Cataract removal	1280	1650	1980
Hip replacement	2808	3666	4274
CABG (3-vessel)	4690	6123	7139

* Plan names withheld because fees were given in confidence to Health Policy Institute by IPA executives.

Several interim remedies are being devised, however. One approach adjusts a few fees that are grossly out of line. Invoking "inherent reasonableness" authority, HCFA uses this approach to reduce payments for "overpriced" procedures. Although corrections have been made for a few services such as cataract removal and installation of pacemakers, most physician payments currently are based on historic trends.

Another approach used by HCFA to control "runaway" costs involves a recalculation of the Medicare Economic Index (MEI), an inflation index for increases in physician office expenses that result from inflation.[7] HCFA estimates that this downward modification in the MEI will save Medicare an increasing amount of money.

Another approach, more far-reaching in concept than the interim measures described previously, but less radical than capitation and physician DRGs, was tried by the Boston University Health Policy Institute (BUHPI) in the fall of 1984.[8] BUHPI compiled a group of 12 Massachusetts surgeons in a pilot effort to develop a complexity-severity index (C/S index) of surgical services, based on professional judgment, that could provide the basis for a relative value scale.

Building this kind of index, although intuitively appealing, proved time consuming and cumbersome. It also raised questions of antitrust. The Federal Trade Commission has barred professional groups from developing relative values guides on the grounds that such guides ". . . established by competitors in a commercial context, probably would constitute illegal price fixing because the dissemination of information and agreement on establishment of price structures usually lead to price uniformity and stabilization."[9]

In this pilot study, BUHPI identified a private corporation that had captured the essence of the C/S index and developed a practical way to convert it to a physician payment management system. The approach of Caterpillar Corporation (CAT), based in Peoria, Illinois, has resulted in the evolution of "degree of difficulty" relative value scales (DODRVS) and regional multipliers that appear to accomplish a pragmatic fee schedule reform. Access to physicians is achieved for CAT employees and their families, and local physician acceptance of the overall CAT process is maximized. Since CAT is not a dominant payer in any geographic area and is not a provider, the potential for antitrust challenges is minimal.

Table 3 shows the close correlation between the C/S index numbers, arrived at through the BUHPI study, and CAT's DODRVS, reached by consultation with regional surgeons. This striking correlation between the two processes suggested to the BUHPI that CAT was on target in its surgical fee activities, and led to the collaborative project described in this paper.

TABLE 3. *BUHPI C/S Index Compared with CAT DODRVS*

	C/S Index	DODRVS
Thoracentesis	3	3.4
Appendectomy	24	26.4
Cholecystectomy (with common bile duct exploration)	48	47.7
Total thyroid lobectomy	40	41.8
Modified radical mastectomy	45	47.7
Colectomy, partial	55	54.5
Pancreatoduodenectomy	100	100.0

The Caterpillar Method

CAT is an international manufacturer of earthmoving machinery and equipment, employing an estimated 54,000 employees in 15 domestic and 13 foreign plants. CAT health benefits cover employees and dependents, as well as 21,000 retirees. The benefit package includes hospitalization, physicians' services, laboratory, x-ray, prescription drugs, and dental and eye care. The CAT health plan is self-insured and self-administered.

In 1983, CAT implemented for its U.S. employees a negotiated fee schedule approach to physician fees for surgical and invasive procedures. The CAT physician payment system emphasizes (1) employee access to a wide range of qualified surgeons, (2) fees negotiated with local surgeons that are considered reasonable and consistent with local market forces, and (3) billing practices review applied consistently to all incoming claims. Particular features of this approach are described below.

Establish a fair fee cap. With input from respected community physicians in locations with a large number of CAT employees, CAT establishes a fair fee cap for surgical services. The CAT method involves convening a limited number of meetings with selected representatives of the surgical community and the CAT medical director for group insurance (CAT M.D.). Where it makes the most efficient use of time, the CAT M.D. meets with individual specialty groups. Operating under a "physician friendly" philosophy and the assumption that physician education and involvement help achieve a mutually agreeable solution, the CAT M.D. describes the situation from CAT's point of view: (1) there are wide variations in fees and billing practices; (2) there is often insufficient documentation to properly process claims; (3) a way is needed to compare the difficulty of various services so their "relative value" can be considered for payment decisions; and (4) a reassessment of the need for surgical assistants is needed.

Actual claims received are used as examples (with patient and provider identities protected). The CAT M.D. then solicits provider input on how problems can be corrected. General consensus is gained on reasonable billing practices and relative degree of difficulty of various procedures, based on recommendations by the CAT M.D. and discussions with physician groups.

Use of geographic multipliers. CAT's DODRVS is combined with a regional dollar multiplier to calculate the actual dollar payment limit. The regional multiplier is based on market research by the CAT M.D. Where there are unusual market conditions for certain specialties, CAT may adjust the multiplier up or down for some services rather than changing the entire region's multiplier. This system allows CAT to take into account the local health care market, legitimate variations in provider billing and medical practices, and variations in the cost of living.

Continual audit and recoding of physician bills. CAT claims processors subject each incoming physician bill to a coding analysis of CPT-4 codes as a first step, and recode claims where irregularities are found. Obvious simple coding errors are corrected first. Individuals with clinical knowledge and judgment then compare the provider's description of services with submitted codes; operative reports are requested for most surgical claims and follow-up calls to provider offices for clarifying information are common. Once the claim reviewer is satisfied that enough information is available to code the bill consistent with CAT procedures, recoding is finalized, and the correct codes are compared with established regional fee schedules. Reviewers with clinical experience consult the CAT M.D. as needed, assuring that a high level of understanding of the surgical experience is applied in the review process.

Tables 4–7 illustrate some features of the CAT process. They are representative of some claims received by CAT.

In Table 4, the appropriate payment is $1000 for code 38100. The patient was hospitalized for an elective splenectomy. The CAT reviewer would disallow codes and

TABLE 4. *Bundling of "Unbundled" Bill*

Procedure	CPT Code	Charge
Splenectomy	38100	$1000
Laparotomy	49000	600
Appendectomy	44950	600
Preoperative check (in hospital)	90215	125
Suture removal	90270	100
Total charge		$2425
Amount paid		$1000

TABLE 5. *Excessive Fee Reduced, Assistant Surgeon Claim Denied as Not Medically Necessary*

Procedure	CPT Code	Charge
Excision biopsy, breast (R)	19120	$1500
Excision biopsy, breast (L)	19120-50	1500
Charge		$3000
Assistant surgeon fee (R)	19120-80	$1200
Assistant surgeon fee (L)	19120-50-80	1200
Charge		$2400
Total charge		$5400
Amount paid		$ 750

charges for all except the splenectomy: a charge for laparotomy and incidental appendectomy is warranted only if done as a separate procedure and preoperative check and postoperative care are conventionally part of the global surgery fee. A charge of $1000 for the splenectomy is in line with the regional fee schedule and is the amount ultimately approved.

In Table 5, the appropriate payment is $750 to the primary surgeon for code 19121 (excision biopsy, breast, bilateral). Under most conditions, one surgeon can perform a breat biopsy. The operative report indicates no unusual circumstances. The assistant surgeon is not reimbursed, and the patient is informed of CAT's review decision.

In Table 6, the appropriate regional payment is $60 for code 17100. The procedure was actually a simple wart removal. The operative report describes a 0.25-inch plantar wart on one foot. Excision combined with use of the laser constitutes excessive treatment for this common condition. Wart removal is most accurately coded as 17100 ("destruction by any method of benign skin lesion").

CAT knows that four local experienced, board-certified cardiac surgeons will carry out a three-vessel coronary artery bypass for $5000, assuring that access can be achieved for that fee (Table 7).

Tables 4–7 demonstrate that complete and knowledgeable recoding of claims requires familiarity with both the content of various surgical procedures and the details of coding surgical services.

Physician negotiations. Individual physician negotiations are carried out for selected claims. After establish-

TABLE 6. *Recoding of Unnecessary Procedure, Excessive Fee Reduced*

Provider Description	CPT Code	Charge
Excision, benign lesion, foot and use of CO_2 laser	11421	$450
Total charge		$450
Amount paid		$ 60

TABLE 7. *Fee Adjustment*

Procedure	CPT Code	Charge
Coronary artery bypass graft, 3 vessel	33512	$8000
Total charge		$8000
Amount paid		$5000

ing an overall fee schedule with local physician representatives, CAT continues its negotiations on a selected claim-by-claim basis. If the amount charged for corrected codes significantly exceeds the regional fee cap, CAT contacts the billing physician, giving information on the corrected codes and the amount allowed. The CAT M.D. makes many of these calls. Usually the provider is willing to accept CAT's recoding and reduced fee. Discussions of claims with physicians have revealed that providers enter practice largely ignorant of common billing practices. Most admit they do not know what various procedures are worth. At best they occasionally may ask other providers what they charge. Those who use an RVS have access only to a wide variety of unstandardized sources. Some are advised to start charging high rates to get a high fee profile. Often, physician offices have an office clerk coding claims who is not trained in medical terms or coding, whereas other physicians rely on central billing services that promise to "maximize reimbursement," often with "creative" upcoding or unbundling of services.

Employee communication. CAT has a program of employee communication that defines the employees' responsibilities and options when payment is less than the fee charged by a surgeon. A letter of explanation is automatically generated to the employee when there has been a payment reduction. It states that if the employee has discussed the fee with the physician before the procedure, the employee is responsible for the amount in excess of CAT's fee cap. Also, employees are told when their provider has agreed to accept CAT's reimbursement as payment in full.

Patient held harmless. If a physician bills an employee for the amount that exceeds the fee cap, the employee is instructed to contact CAT, and a CAT provider relations specialist discusses the situation with the physician. Patients are not required to pay the physicians' balance bill above the CAT payment (that is, they are "held harmless") if the physicians have not informed the patients of the higher-than-cap fee before the procedure. CAT intervenes on the patient's behalf when the physician refuses to lower his/her fee to the established cap. On average, of about 20,000 physician claims received per year, CAT has less than a dozen instances in which providers insist on trying to obtain reimbursement above the CAT fee through claims court. In over 95% of

these cases, the judge has agreed that CAT's payment is reasonable for the services, based on local surgeon input.

Study of Savings with CAT Method

CAT's internal calculations indicate that it achieves significant savings with its surgeon bill review process by reducing fees that otherwise would have been paid in full. The BUHPI is conducting an external evaluation of the CAT process for managing surgeon fees. Standard surgical fee processing by large insurance companies and third-party administrators is being compared with the potential cost savings of the CAT process. The BUHPI has obtained samples of consecutively filed claims for surgical services that have been processed for several large self-insured corporations that administer their claims through major insurance carriers. The benefit plans establish payment caps at a percentile of usual and customary fees, and the carriers' auditing of codes was representative of current industry standards. CAT's recoding and bundling procedures, as well as payment caps, were applied to these claims, with the goal of finding if the savings from payment reduction significantly exceeded those achieved by these carriers.

Hard copies of the providers' originally submitted claims were processed by CAT staff without information about changes from charges that had been made by the carriers before these claims had been paid. Confounding variables of payment due to copayments, deductibles, or coordination of benefits were eliminated.

The total charges included in the sample claims were over $140,000. The carriers adjusted 13 to 15% of their claims and paid 4.3 to 35% less than total charges. CAT adjusted 35 to 40% of these same claims and reduced payment from charges by 22 to 43%. Therefore, CAT would have achieved an additional savings of 8 to 17.7% if CAT's procedures and the lower of CAT or the administrator's fee schedule were used. One third of the additional savings came from coding changes in the original bills and two thirds by the application of the CAT negotiated fee schedule. In some instances providers submitted an incorrect code that significantly *undervalued* the procedure that was done. If the provider's code had been used, the payment would have been cut to an unreasonable level. In these instances, the CAT reviewer "upcoded" to the correct code and allowed the more appropriate fee; the savings potential includes these corrections in favor of billing surgeons.

Discussion

The CAT system for managing surgeons' fees has been developed by a progressive benefit department in a large American corporation. The system depends on detailed knowledge of surgical practice so that recoding and bundling of procedures categorized by CPT-4 codes can be accurately carried out. It requires contact with local surgeons in regions with a high concentration of employees so that market forces can be taken into account in determining an appropriate level of local fees.

An access-oriented negotiated fee schedule can have many permutations. In areas with a surgeon surplus, a corporation may be able to negotiate lower fees with surgeons than those previously paid. In areas with few surgeons, fees lower than customary are more likely to create patient access problems should the surgeons resist reductions negotiated elsewhere. Still, modified versions of CAT's approach would be similar to processes already used by the government in establishing "inherent reasonableness" for cataract extraction and pacemaker installation fees.

The key concern about any new surgeon payment approach should be the ability to attract a good representation of local surgeons who will accept it. Ensuring employees' access to qualified surgeons is the paramount goal. All other considerations, even inherent reasonableness of lower fees because of technological advantages or cost containment, should remain secondary.

Based on the BUHPI's analysis, the CAT process is a workable and market-tested solution to the need to balance access and cost management. It is suitable for large corporations such as CAT with both self-funded and self-administered health benefits. It can also be used (after eligibility is certified and benefits are coordinated) by claims processing systems. Accurate implementation of the CAT process requires (1) hard copies of the CPT-4 codes submitted by the surgeon and availability of the operative notes, to reconcile discrepancies between CPT-4 codes and the surgical service, and (2) access-oriented negotiated fee schedules obtained by applying a geographic multiplier to an RVS, such as CAT's DODRVS.

State and federal governments can modify the CAT process for Medicaid and Medicare, with the same goals that motivate the private sector: access and cost management. Regional fee schedules could be established with national DODRVS values and regional multipliers based on market forces. Balance billing is optional, using the CAT model. However, its effectiveness as a cost management approach is strengthened with its "hold harmless" provision. In the CAT system, if a patient knows a surgeon is charging a fee higher than the negotiated fee, the patient is responsible for the balance. If no discussion has occurred, the patient is held harmless for bills in excess of the fee cap.

If adequate access is to be preserved without the need for balance billing, payments must be established so that a majority of qualified surgeons in each region will accept the negotiated fee as payment in full. If this acceptance is not achieved, then access problems will arise, as

TABLE 8. *Comparison of "Resource-based Relative Value Scale" (RBRVS) and "Access-oriented Negotiated Fee Schedule" (AONFS) for Physician Reimbursement**

	RBRVS (Hsiao)	AONFS (CAT)
Goal	A "comparable worth" reform for physicians, a group with high incomes relative to most other occupations.	Patient access to local physicians at a negotiated price.
Methodology	Complex formula determines RBRVS; time is a major determinant.	Revision of fees is based on negotiations, M.D. fee acceptance patterns (market forces, not payment of charges).
Application	Two basic problems: (1) RBRVS is not a fee, and knowledge is needed of regional situations to use multiplier effectively. (2) when applied in Massachusetts, shown to need extensive modification to get support of, and access to, local surgeons.	In routine use. CAT knows that well-qualified local physicians will accept the AONFS.

* AONF = DODRVS × regional multiplier.

occurred in 1986 for the Massachusetts Medicaid program. That program was forced to increase significantly its fees for normal deliveries. As stated in the *Boston Globe*, ". . . responding to a crisis in access to obstetrical care in many areas of the state, the panel hiked the all-inclusive fee for pregnancy care and childbirth from $508 to as much as $1,200."[10] This is a good example of the futility of a fee schedule that does not build on knowledge of physicians' availability at different fee levels in each region. The Massachusetts Medicaid program had a previous experience with attempting to introduce a fee schedule based on a "resource-based" formula.

In July 1983, the *Boston Globe* described a new strategy that was suggested by the Massachusetts Rate Setting Commission for the Medicaid program and workers compensation.[11] Based on the 1979 study by Drs. Hsiao and Stason from the Harvard School of Public Health,[12] the Rate Setting Commission proposed that the fees for 21 common surgical procedures should be cut by amounts ranging from 4% to 59%. At the same time, physicians seeing patients in their office were to get 71% more for initial visits. These proposed changes were the estimated relative resource requirements of different physician services, with a strong focus on the time involved. The formulas were established in the Hsiao/Stason analysis of physician practices.

These changes were adopted in September 1983, but on August 23, 1984, the Rate Setting Commission raised the fees that the state Medicaid program paid to doctors for surgical procedures. As stated in the *Boston Globe*, "no prior hearing was held or public notice given before the August reversal because the Commission subsequently said physician resignations from Medicaid had reached the level of a public health emergency. Most striking of these defections were obstetricians/gynecologists."[13] This experience suggests that fees ultimately paid by Medicaid were primarily driven by the need to get access to Medicaid patients to physicians, and not by a formula for "resource costs."

The American Society of Internal Medicine and the American Medical Association have supported an elaborate study of the Hsiao methodology commissioned by HCFA, and there is much speculation about the possible use of an RBRVS for the determination of Medicare fees when it becomes available in the summer of 1988. The investigators of the BUHPI originally believed that the consensus process to determine a C/S index could be developed as the basis for fee reform that would be acceptable and perceived as fair by physicians. However, the consensus approach is laborious, and much time would have been necessary to interrelate all specialties and resolve potential conflicts. It was then that the BUHPI began to study the CAT system, and found that it involved a process with appropriate goals, methodology, and application for cost management and market acceptance.

Table 8 outlines the basic differences between a "resource based" RVS and an access-oriented negotiated fee schedule, as used by CAT. A basic goal of the RBRVS is to "reform" physician reimbursement in the direction of more equity between procedure-oriented specialists and generalists. However, as the evidence suggests, this goal will be in conflict with realities of the marketplace and will result in paying fees that are either unnecessarily high or too low to get ready access for insurees to local physicians.

The methodology of the RBRVS is based on a formula unrelated to local market forces, whereas the access-oriented negotiated fee schedule used by CAT builds on negotiations and local fee acceptance patterns to gain access. The CAT system's ability to adjust for regional differences in the market is the essential difference in the two approaches. The CAT system is in routine use and will continue to be modified by changes in local physician manpower and other factors such as increases in malpractice premiums. We suggest that an access-oriented negotiated fee schedule such as the CAT system deserves consideration as the preferred method of fee reform.

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References

1. Waldo DR, Levit KR, Lazenby H. National health expenditures, 1985. Health Care Financing Review 1986; 8:14.
2. Physician Payment Review Commission. Medicare Physician Payment: an Agenda for Reform. Annual Report to Congress. Washington DC: U.S. Government Printing Office, March 1, 1987.
3. Knox RA. Study on Equalizing Medicare Bills Begins. The Boston Globe, September 13, 1985; 4.
4. Congress of the United States. Physician Reimbursement Under Medicare: Options for Change. Washington DC: Congressional Budget Office, April 1986.
5. Congress of the United States. Payment for Physician Services: Strategies for Medicare. Washington DC: Office of Technology Assessment, February 1986.
6. Jencks SF, Dobson A. Strategies for reforming medicare's physician payments: physician diagnosis-related groups and other approaches. N Engl J Med 1985; 312:1492–1499.
7. Dutton BL, McMenamin P. The medicare economic index: its background and beginnings. Health Care Financing Review September 1981; 3:137–139.
8. Egdahl RH, Manuel B. A consensus process to determine the relative complexity-severity of frequently performed surgical services. Surg Gynecol Obstet 1985; 160:403–406.
9. Pollard MR. Anti-trust and Physician Payment. Reforming Physician Payment 1984. Institute of Medicine: Report of a Conference. Washington DC: National Academy Press, 1984; 75–86.
10. Knox RA. Proposal Would Raise Medicaid Fees. The Boston Globe, April 17, 1986; 27.
11. Knox RA. Medicaid Fee Shifts Adopted. The Boston Globe, September 16, 1983; 17.
12. Hsiao WC, Sisson WB. Toward developing a relative value scale for medical and surgical services. Health Care Financing Review, Fall 1979; 1:23–38.
13. Knox RA. State Shifts on Medicaid Fee Cuts. The Boston Globe, September 27, 1984; 1.

Discussion

DR. W. GERALD AUSTEN (Boston, Massachusetts): I congratulate Drs. Egdahl and Hertenstein on an excellent and stimulating paper. They have worked long and hard on physician payment reform, and they recognized early the importance of physician acceptance in any proposed reform. Thus, a major element of the current proposal includes the active participation of the physicians.

Three and a half years ago, the Regents of the American College of Surgeons created a Committee on Physician Reimbursement of which I have been Chairman. This committee, with much input from the surgical specialty societies, has developed recommendations for the reform of the Medicare physician payment program, and these recommendations were approved by the Regents in October 1986.

The aim of the College, like the approach presented today, is to identify ways to achieve a more rational payment system with cost savings and at the same time ensuring adequate access to quality care.

The ACS approach has a number of similarities to the program presented this morning; the ACS proposal includes the creation of a Medicare relative value scale based on physician charge data and with modifiers based on geographic differences in practice costs, the definition of payment units with emphasis on a global fee and the creation of definitions and guidelines to determine when an assistant at surgery for Medicare payment purposes is necessary.

I have one question for the authors. The Caterpillar Corporation has approximately 50,000 employees in 15 domestic plants, and it also has a very persuasive, sensible medical director. How would you expand your proposal from one company to a national program?

Finally, I would like to add that it is crucial that surgery be involved as much as possible in the current debate on physician reimbursement reform, and we need to be able to present sensible and fair approaches backed by solid data. The next year and a half is probably going to be crucial.

I would urge Drs. Egdahl and Hertenstein to continue to gather information and to make every effort to present their data and recommendations to the appropriate congressional committees and to the Administration.

DR. OLIVER H. BEAHRS (Rochester, Minnesota): Drs. Egdahl and Hertenstein have done us a favor by developing and reporting a modification of the CPR fee for service reimbursement for surgical services. I appreciate the opportunity to have read the manuscript.

Their program, which is a negotiated access RVS, is in contrast to the Harvard–AMA resource based RVS, and is being developed under contract from HCFA. This RVS is of concern because of the inordinate weight given to time as a factor and the methodology being used.

There is great anticipation regarding this study in Washington and some are thinking of it as the only game in town.

The Physician Payment Review Commission (PhysPRC) established by Congress in 1986 made its first report to Congress on March 1, 1987. The Commission supports a fee scale based on a national RVS with appropriate regional multipliers to determine fees. The basis for the RVS has not been determined, but hopefully it might be based somewhat on historic charges and not the strictly resource criteria of the based parameters used in the Harvard Study.

The use of the CPT-4 Code has come under criticism: first a dictionary of 2000 codes, and now 7000 and with multipliers 48,000. It was established primarily for medical record keeping and to establish charges. It has led to unbundling of services and upcoding to establish fee for services. This practice has led to excessively high fees in at least 10% of cases because of unbundling or upcoding.

I would be interested in the author's suggestions how the CPT-4 codes might be collapsed or bundled and what policy could be established to prevent these abuses.

A long-term program for physician payment is probably several years away and may be a fee scale hopefully, but there is administrative and congressional support for capitation or voucher arrangement, possibly DRGs. Congress is looking for a near-term solution to its budget problem for 1988.

The budget mark-up will be in the next few weeks and the recommendations to meet the cut almost certain in physician reimbursement will be in place by September.

The reduction in reimbursement might be another freeze, a shaving downward of the medical economic index, selecting the highest outliers such as coronary artery bypass, hip reconstruction, and/or TUR for across-the-board decreases as was done to cataract surgery in 1986 and 1987, or selective decrease in the high rollers or by addressing the reduction by using the inherent reasonable rule that is already in legislation.

My second question to Dr. Egdahl and Dr. Hertenstein is what are your recommendations in the next month or two to meet the 1988 budget limits?

DR. MARTIN ALLGOWER (Basel, Switzerland): I appreciate the invitation to look "with a Swiss eye" at the presentation of Dr. Egdahl.

In Switzerland it is said that the surgeon goes through two stages. At the beginning of his career, collecting a fee, he gets red in the face. Later on his face reddens when he does not get paid!

The Swiss economic system is a rather complex mixture of free enterprise and institutions run almost exclusively by public bodies. We consider many of the things you do not as public responsibilities. These include post and telephone services, railway services, schooling and university formation, and most hospitals are run by local government agencies. The health care system is furthermore complicated by the fact that insurance conditions for accidents are very different from

those for diseases. It is obvious that this difficult distinction keeps our lawyers busy!

Basically, surgeons are mostly employed on a geographical full-time basis in a state hospital. Those state hospitals, however, have private, semiprivate, and general wards. This, I believe, is a rather favorable arrangement, combining a salaried position for the administrative obligations as well as for the care of the general patient with a fee-for-service system for the private patients. Now, comparing this with the cap system, we find great similarities because the Union of Swiss Surgical Societies, including all specialties, has set up a range of fees that may be reasonably asked from a patient or from the insurance, *i.e.*, the third party paying. Those ranges, just to give you an idea, would range from 400 to 1000 francs for an appendectomy, for a gallbladder from 1000 to 2000 francs, and for major operations such as a total gastrectomy, a Whipple, an acetabular repair or a resection of an abdominal aneurysm, from 3000 to 6000 Swiss francs. That is about the maximum fee we are allowed to ask or, at least, that the Union will support, if it is contested in court. You may divide the figures by 2 to arrive at dollar values, because that is about the realistic comparison in terms of buying power.

It is a fairly democratic self-regulating peer-controlled system. What we dislike in Switzerland is the "big brother" state watching us and telling us what to do.

We have one advantage over you. The contingency system is unacceptable and the one party who loses "the battle" usually has to pay the other's legal expenses. That often prevents people from going to court, although there has been a definite increase in liability claims in recent years.

Overall our system results in an average income of some 300,000 to 400,000 francs for a Swiss surgeon. Out of that he pays some 50% in taxes. Our rather democratic system is similar to what Dr. Egdahl has just presented. It is based on a fee for service "common sense scale," the majority of surgeons working in a geographical full-time scheme.

DR. WILLIAM R. DRUCKER (Rochester, New York): I appreciate the opportunity I had to review this paper. Dr. Egdahl has given us a clear presentation of an industry-sponsored plan that attempts to gain physician compliance with a method of reducing costs of medical care through reduction in fees.

It is a very clear example that in addition to government today, our health care system is being strongly influenced by industry.

I have a couple of editorial comments and then a couple of questions. The major factor in the rise in health care costs is not physician fees. This is simply illustrated by a look at the average fees of physicians across the country, somewhere in the range of $50,000–$150,000. I realize that others make considerably more, but each physician can be estimated to cost the health care system something in the order of three quarters of a million dollars per year by the exercise of his physician rights in doing his job of taking care of patients. Therefore, the major target that needs to be addressed is physician behavior, not physician fees. Nevertheless, fees are perceived as a problem that is going to be addressed whether we like it or not.

I wonder whether this paper is simply the expression of a last gasp hope that current physician fees and the fee for service system will continue. I sincerely hope this is not its purpose and I believe Dr. Egdahl agrees based on the way he has presented the paper. My reading from the paper is that Dr. Egdahl is presenting a plan that is asking clearly for physicians to get together and plan to help solve the problem of fees rather than having it done for us by external agencies; that it stems industry and government.

My questions are these. They are straightforward, I believe, and can be answered simply. What will happen in the case of an emergency when one of the patients in the system under the cap must have an emergency operation and they seek a doctor who does not agree with this system: would this be settled in claims court?

What about quality? Does the system depend on the physician participants to ensure quality or do they have other ways to ensure that their employees are obtaining the quality of care that they would under the current system of fee selection.

How about comparison with other systems? Has there been enough experience to date to show that this system is gaining popularity? Is there any way to compare this system with others in terms of two factors: physician acceptance to work in the system, and employee acceptance of this system for their health insurance?

Then there is a question of cost. This is a very complex system. It seems very costly if one reads carefully. What is the cost? Is there any estimate of what the cost would be of setting up and maintaining this system that requires close scrutiny of all bills that come in; a very complex system of monitoring these bills? Is the billing method unique to CAT or can other insurance systems do this too? Is this system for sale? Do other insurance companies look at claims this carefully?

DR. BENSON B. ROE (San Francisco, California): Dr. Egdahl is to be thanked for bringing to our attention a sensible proposal to address a serious threat to the fee-for-service system. I believe we finally are all aware of this threat, and I am delighted that we are prepared to gather our forces to get behind something positive.

About 8 years ago I became aware of the enormity of the abuses in the current system that were taking place, perhaps not by the respectable members of our profession but by an alarming number of those who did the kind of unbundling and some of the things that he showed you. I published an article that was intended to stir us to take some initiative in this problem rather than hoping it would go away. I hope it is not too late.

It is equally important that we get behind some system that establishes fiscal integrity so that we do not jeopardize the precious and unique privilege that we have of self-governance. This privilege is threatened by the behavior of some of our colleagues who have abused the system and brought this problem to our attention.

In addition to the proposals that Dr. Egdahl has made, I believe we should place emphasis on the magnitude of responsibility to cover not only accessory procedures but complications. No one can tell me whether my complication was part of the patient's underlying disease or could possibly be one from some flaw in my technique or management. We should accept as a part of our primary responsibility the full scope of managing a patient from start to finish without throwing in extra for everything that can be imagined. If we had done that, we would have reduced our total cost to the public by at least 20%.

DR. JAMES R. JUDE (Miami, Florida): I rise because I am confronted by patients who are faced with billing problems after hospital discharge. One of the problems is the unbundling that Dr. Egdahl has brought up.

Ten years ago on an Ethics Committee of our local medical society we, out of hand, tossed unbundling out as a completely immoral approach to any type of billing. I did not believe it even could possibly exist any more, but there is more of a problem than just the bundling together of the surgical fee. The problem is much greater than that. We always keep our office open to speak to any patients about any problems, and it is very common for them to present with bills of what really amounts to an unbundling of the bills of other physicians who were involved in their treatment.

Most commonly this has applied to anesthesiology, which frequently approaches 50% of the surgical fee. It is not, however, only the anesthesiologists, it is also the internists, the radiologists, the pathologists, and possibly the cardiologists who are reading electrocardiograms. Patients receive an enormous number of bills from physicians, and so it is a total physician unbundling and not just a surgical fee unbundling that is occurring.

Some way or other we have to approach the problem whereby there will be some type of bundling together of all physician fees in a package.

As our President presented yesterday in his Presidential Address, many treatments that we do are not all surgical anymore, but rather a blending over into medicine, and medicine is delivering surgery and surgery is delivering medicine. Therefore, we should give a great consideration to the total care and the total charge.

Dr. Egdahl, what if anything have you considered about these other fees in respect to a global cap or other industry approaches to the total cost of care in surgery?

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DR. JONATHAN E. RHOADS (Philadelphia, Pennsylvania): I listened to this paper with a great deal of interest. I would emphasize that if most people have a 50% overhead, that a 15% reduction in fee is a 30% reduction in take-home remuneration. That is well to keep in mind.

There is one aspect of the overhead that has gotten bigger and that is liability insurance. This in a way is the loose cannon on the deck, and when you have a fee schedule set, whether by government or by consent, and this expense is assumed to be something that the physician will pay, you have an unpredictable situation.

I raise the question and ask the authors if there is any precedent for malpractice insurance being billed on a per case basis or a percentage of the fee. No doubt this would require the insurance company to have access to one's tax returns and so forth to be sure that it was honest, but it would have certain great advantages. It would permit the young physician starting out to start out on his own, pay his share of the liability costs, but not be expected to pay immediately the same amount that a person would be paying who is doing 10 times as much work in the middle of his career.

Perhaps the far greater advantage in my belief is that this could appear and should appear as a separate item on the bill.

I can think of no way that would educate more of the public as to the true cost of liability insurance than to have a bill (operation $300, insurance $125, or whatever it might come to).

I rose to raise this issue and to ask the authors if they knew if there was any precedent for such a plan and to ask whether they believe there is any way this could be tried out before we get tied into a fee schedule system with an unpredictable cost for liability insurance.

DR. RICHARD H. EGDAHL (Closing discussion): Dr. Austen's question about the possibility of expanding the Caterpillar program as it now exists to a national level is an important one. The problem is that major national programs such as Medicare necessarily involve a large bureaucracy, whereas a private self-administered company such as Caterpillar does not require the same degree of routinization of operations and an easily replicated methodology. The country could certainly be divided into 6–12 regions, each consisting of several states. I do not know whether appropriate flexibility could be built into the management and technical components of the administrative structure which would be part of a national program.

Dr. Beahrs raises questions about the future use of CPT-4 codes and asks what we can do in the short range to control outlier Medicare fees. I believe we can use CPT-4 as long as we understand the basis for matching up the procedures that actually were carried out with the codes, and have some way to ratchet downward those charges that seem inappropriate. Certainly there are a few groups selling systems with the goal of achieving code creep, which is basically dishonest. On the other hand, the majority of codes that are incorrect represent simple errors based on the difficulty of each doctor's office knowing all the technicalities of coding. We can stick with CPT-4, but must match the operative note with the CPT-4 code, using physician judgment to determine if the code is appropriate. The short-term answer for HCFA is to expand the principle of inherent reasonableness, which thus far has been limited to a few surgical conditions. Another 20–30 big-ticket items that appear to be out of line could be revised downward or upward.

Dr. Martin Allgöwer from Basel talked about the Swiss system and the apparent success of physician-sickness fund negotiations. This type of negotiation, with the government playing a catalytic role, might have relevance to the U.S. system in the private sector. However, Medicare will probably demand a closer involvement in the process than exists in Switzerland, since the government is paying the bill directly.

Dr. Drucker asked a key question about what happens in emergencies under the Caterpillar system. Usually Caterpillar pays charges in emergencies, but also has a strategy involving clearance for appropriateness of treatment in emergencies, when there is time. If gross overcharges are billed, even for emergency situations, and local surgeons support that the charges are unreasonable, then payment of those charges can be challenged.

Dr. Roe discussed his analysis of fees, and raised the question about possible antitrust issues if physicians are in the position of commenting on the appropriateness of their fees. Industry does not want to see private medicine nationalized, but could turn on us if we do not cooperate in developing a rational method of physician reimbursement. The key to not raising antitrust issues is for surgeons to act as individual consultants to payers who determine those fees, such as large industry.

Dr. Jude asked about how to get our internist colleagues involved in the process of fee negotiations. We found in our complexity/severity work with the Massachusetts Chapter of the American College of Surgeons that we could relatively easily get consensus on the "relative value" or "complexity/severity" of surgical services among that group. We then talked to internists and achieved some preliminary agreements; for example, an "intermediate acute myocardial infarction," from the time a patient comes into the emergency room, is taken into the critical care unit, and discharged, appeared to be similar in complexity/severity to an uncomplicated cholecystectomy, from initial diagnosis through discharge from the hospital after surgery. Reimbursement for some general medical conditions can be converted into a global fee, but for many medical conditions it is a more difficult process than for surgical cases.

Finally, Dr. Rhoads talked about malpractice problems associated with surgery. I return to the principal goal of Caterpillar and its fee process, which is access for their employees and their families to a significant number of high-quality local surgeons. Overall, malpractice problems will probably get worse before they get better. A solution will flow from severe access problems in different parts of the country, and a realization by both legislators and the public that the ordinary rigors of surgical practice are being compounded manyfold by additional financial and psychological pressures from the omnipresent danger of malpractice suits. We suggest that the Caterpillar process of negotiating access-oriented maximal fees with local surgical groups represents a reasonable compromise between paying charges, on the one hand, and accepting a formulaic-driven fee schedule not negotiated with some local physicians with access as a goal, on the other hand.

Increases in malpractice premiums will result in increased surgical fees, or the public will not have available the surgeons that they want in the variety of practice sites and numbers of specialties that are desired. We have only a modest amount of time before HCFA and the Congress will take some kind of action on fees, as they have on hospital reimbursement under Medicare. Industry can be our strongest ally in achieving a workable system of access-oriented negotiated fees.

EXHIBIT C

4:1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAYO FOUNDATION FOR MEDICAL EDUCATION & RESEARCH, a Minnesota charitable non-profit corporation,	)	
Plaintiff,	)	
v.	)	Civil Action No. 97-423-RRM
FONAR CORPORATION, a Delaware corporation,	)	
Defendant.	)	

ORDER DENYING PLAINTIFF'S MOTIONS TO DISMISS COUNTERCLAIM, TO STRIKE AFFIRMATIVE DEFENSES, AND FOR MORE DEFINITE STATEMENT

This is a patent case. Plaintiff Mayo Foundation for Medical Education and Research ("Mayo") is a non-profit Minnesota corporation with its principal place of business in Rochester, Minnesota. Mayo owns U.S. Patent No. 4,715,383 ("the '383 patent"). Defendant Fonar Corporation is a Delaware corporation with its principal place of business in Melville, New York. On July 18, 1997, Mayo filed a complaint alleging that Fonar has willfully infringed, has induced others to infringe, and has contributorily infringed the '383 patent. On January 2, 1998, Fonar filed an answer denying infringement and asserting several affirmative defenses, including that Mayo's suit is barred by the equitable doctrines of laches, estoppel, and waiver. Fonar

also filed a counterclaim stating that "[t]he '383 patent is invalid and unenforceable because it fails to satisfy the requirements contained in 35 U.S.C. §§ 41 and 101 et seq., including but not limited to, §§ 102, 103, and 112."

On January 21, 1998, Mayo filed a motion to dismiss the counterclaim on the ground that it "fails to allege any facts upon which relief can be granted," and to strike the affirmative defenses on the ground that "defendant has not alleged any fact, which with all reasonable inferences, constitutes a sufficient defense." Mayo also moves, alternatively, for an order for a more definite and certain statement of the counterclaim and defenses.

Federal Rule of Civil Procedure 8(a) requires that a pleading set forth "a short and plaint statement of the claim showing that the pleader is entitled to relief." Rule 8(b) requires a party to state its defenses "in short and plain terms." The court finds that Fonar has complied with these rules. Thus, the court will deny Mayo's motions.

Mayo argues that it will be unable to prepare its case without a better understanding of Fonar's counterclaim and defenses. However, the appropriate means for achieving this understanding is discovery. Mayo should utilize the appropriate discovery strategies permitted by the Federal Rules.

For the reasons set out above,

IT IS HEREBY ORDERED as follows:

1. Plaintiff's motion to dismiss defendant's counterclaim (D.I. 8) is denied.

2. Plaintiff's motion to strike defendant's affirmative defenses (D.I. 8) is denied.

3. Plaintiff's motion for a more definite statement of defendant's counterclaim and defenses (D.I. 8) is denied.

UNITED STATES DISTRICT JUDGE

Date: August 19, 1998

CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that copies of the foregoing were caused to be served on December 7, 2004 upon the following in the manner indicated:

BY HAND

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